11–19–99
Vol. 64 No. 223
Pages 63171–63560

Federal Register

Friday
November 19, 1999

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WHERE: Office of the Federal Register
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RESERVATIONS: 202–523–4538

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 98–083–7]

Mediterranean Fruit Fly; Removal of Quarantined Area

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the Mediterranean fruit fly regulations by removing the quarantined area in Orange County, CA, from the list of quarantined areas. The quarantine was necessary to prevent the spread of the Mediterranean fruit fly to noninfested areas of the United States. We have determined that the Mediterranean fruit fly has been eradicated from this area and that restrictions on the interstate movement of regulated articles from this area are no longer necessary. This action relieves unnecessary restrictions on the interstate movement of regulated articles from this area. As a result of the interim rule, there are no longer any areas in the continental United States quarantined because of the Mediterranean fruit fly.

EFFECTIVE DATE: The interim rule became effective on August 27, 1999.

FOR FURTHER INFORMATION CONTACT: Mr. Michael B. Stefan, Operations Officer, Invasive Species and Pest Management, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1236; (301) 734–8247.

SUPPLEMENTARY INFORMATION:

Background

In an interim rule effective August 27, 1999, and published in the **Federal Register** on September 3, 1999 (64 FR 48245–48246, Docket No. 98–083–6), we amended the Mediterranean fruit fly regulations (contained in 7 CFR 301.78 through 301.78–10) by removing the quarantined area in Orange County, CA, from the list of quarantined areas in § 301.78–3(c). That action relieved unnecessary restrictions on the interstate movement of regulated articles from this area. As a result of that action, there are no longer any areas in the continental United States quarantined because of the Mediterranean fruit fly.

Comments on the interim rule were required to be received on or before November 2, 1999. We did not receive any comments. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived the review process required by Executive Order 12866.

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

PART 301—DOMESTIC QUARANTINE NOTICES

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 7 CFR part 301 and that was published at 64 FR 48245–48246 on September 3, 1999.

Authority: 7 U.S.C. 147a, 150bb, 150dd, 150ee, 150ff, 161, 162, and 164–167; 7 CFR 2.22, 2.80, and 371.2(c).

Done in Washington, DC, this 16th day of November 1999.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–30224 Filed 11–18–99; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–ANE–19–AD; Amendment 39–11422; AD 99–23–26]

RIN 2120–AA64

Airworthiness Directives; General Electric Aircraft Engines CF34 Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to General Electric Aircraft Engines (GE) CF34 series turbofan engines, that currently requires installation of a main fuel control (MFC) that incorporates a flange vent groove and installation of an MFC with improved overspeed protection. This amendment requires replacement of Buna-N O-rings with Viton O-rings or a new location of the vent groove on the MFC mounting flange, or installation of an MFC with improved overspeed protection. This amendment is prompted by the determination that the location of the reworked vent groove was ineffective, and that replacement of Buna-N preformed packings with Viton preformed packings will alleviate the unsafe condition. The actions specified by this AD are intended to prevent uncommanded engine accelerations, which could result in an engine overspeed, uncontained engine failure, and damage to the airplane.

DATES: Effective December 6, 1999.

The incorporation by reference of GE Alert Service Bulletins (ASB's) No. A73–33, dated November 21, 1997; A73–33, Revision 1, dated May 29.1998; and A73–19, Revision 1, dated February 20, 1998, was approved by the Director of the Federal Register as of July 27, 1999.

The incorporation by reference of GE ASB No. CF34AL 73–A0025, dated July 7, 1999; CF34BJ 73–A0040, dated July 7, 1999; CF34AL S/B 73–0026, dated August 12, 1999; and CF34BJ S/B 73–0041, dated August 12,1999, is approved by the Director of the Federal Register as of December 6, 1999.

Comments for inclusion in the Rules Docket must be received on or before January 18, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–ANE–19–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: ''9-ane-adcomment@faa.gov.'' Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in this AD may be obtained from GEAE Technical Publications, Attention: N. Hanna MZ340M2, 1000 Western Avenue, Lynn, MA 01910; telephone (781) 594–2906, fax (781) 594–0600. This information may be examined at the FAA, New England Region, Office of the Regional Counsel, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman Brown, Controls Specialist, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7181, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: On May 17, 1999, the Federal Aviation Administration (FAA) issued airworthiness directive (AD) 99–11–08, Amendment 39–11179 (64 FR 28905, May 28, 1999), to require, within 800 hours time in service (TIS) or 120 days after the effective date of that AD, whichever occurs first, installation of an MFC incorporating a flange vent groove. In addition, that AD requires installation of an MFC with improved overspeed protection for: CF34–3A1 and –3B1 series engines, installed on Canadair Regional Jet airplanes, within 4,000 hours TIS after the effective date of that AD, or 24 months after the effective date of that AD, whichever occurs first; and for CF34–1A, –3A, –3A1, –3A2, and –3B series engines, installed on Canadair Challenger airplanes, at the next hot section inspection, or within 60 months after the effective date of that AD, whichever occurs first. That action was prompted by reports of rapid uncommanded engine acceleration events. That condition, if not corrected, could result in uncommanded engine accelerations, which could result in an engine overspeed, uncontained engine failure, and damage to the airplane.

Events Leading to this AD

Since the issuance of that AD, the engine manufacturer has informed the FAA that GE CF34 Alert Service Bulletin (ASB) No. A73–18, Revision 1, dated September 24, 1997, and CF34 ASB No. A73–32, Revision 1, dated September 24, 1997, that describe procedures for reworking MFC's by adding a flange vent groove were in error and had incorrectly located the flange vent groove. Also, the manufacturer has determined that replacement of the Buna-N preformed packings (O-rings) with Viton O-rings will achieve a similar level of safety as the installation of an MFC with a correctly located flange vent groove.

Manufacturer Service Information

The FAA has reviewed and approved the technical contents of GE CF34 Alert Service Bulletins (ASB's) No. CF34AL 73–A0025, dated July 7, 1999, and CF34BJ 73–A0040, dated July 7, 1999, that describe procedures for replacement of the Buna-N preformed packings; CF34AL S/B 73–0026, dated August 12, 1999, and CF34BJ S/B 73–0041, dated August 12,1999, that describe procedures for installation of a reworked MFC with a relocated pressure relief groove; and CF34 ASB No. A73–19, Revision 1, dated February 20, 1998, and CF34 ASB No. A73–33, dated November 21, 1997, that describe procedures for installation of a reworked MFC with improved overspeed protection.

Differences Between the ASB's and this AD

The GE ASB's allow the MFC on CF34–1A, –3A1, and –3A2 engines to be used until the MFC is removed for cause and then replaced with an MFC with a relocated vent groove. Because of the possibility that an unsafe condition may develop, this AD requires that the MFC be replaced with an MFC with a relocated vent groove when the MFC is removed for any reason.

Requirements of this AD

Since an unsafe condition has been identified that is likely to exist or develop on other General Electric (GE) CF34 turbofan engines of the same type design, this AD supersedes AD 99–11–08 to require either replacement of Buna-N O-rings with Viton O-rings or replacement of the MFC with an MFC with a relocated vent groove within 30 days after the effective date of this AD. The actions are required to be accomplished in accordance with the service bulletin described previously.

Immediate Action

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Request for Comments

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 98–ANE–19–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation

that must be issued immediately to correct an unsafe condition in aircraft, and is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety,

Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Amendment 39–11179, (64 FR 28905, May 28, 1999), and by adding a new airworthiness directive, Amendment 39–11422, to read as follows:

AD 99–23–26: Amendment 39–11422: Docket 98–ANE–19–AD. Supersedes AD 99–11–08, Amendment 39–11179.

Applicability: General Electric (GE) CF34–1A, CF34–3A, –3A1, –3A2, and CF34–3B and –3B1 series turbofan engines, installed on but not limited to Bombardier, Inc. Canadair airplane models CL–600–2A12, –2B16, and –2B19.

Note 1: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent uncommanded engine accelerations, which could result in an engine overspeed, uncontained engine failure, and damage to the airplane, accomplish the following:

Replacement Requirements

(a) If the main fuel control (MFC) part numbers (P/N's) 6078T55P02, 6078T55P03, 6078T55P04, 6078T55P05, 6078T55P06, 6078T55P07, 6078T55P08, 6078T55P09, 6078T55P10, 6078T55P12, 6078T55P13, 6078T55P14, 6078T55P15, or 6078T55P16 installed, and if the MFC has Buna-N preformed packings (O-rings), P/N's R1307P020 and R1307P141, do one of the following:

(1) Replace Buna-N O-rings with Viton O-rings, P/N's M83485–1–020 (M83485/1–020) and 37B201714P130, within 30 days after the effective date of this AD, in accordance with the Accomplishment Instructions, paragraph 3.A., of alert service bulletin (ASB) CF34AL 73–A0025, dated July 7, 1999 or ASB CF34BJ 73–A0040, dated July 7, 1999. Or,

(2) For all CF34–3A1 engines with serial numbers (SN's) 807001 and up, CF34–3B engines with SN's 872001 and up, and CF34–3B1 engines with SN's 872001 and up, with main fuel control (MFC) part numbers (P/N's) 6078T55P02, 6078T55P03, 6078T55P04, 6078T55P05, 6078T55P06, 6078T55P07, 6078T55P08, 6078T55P09, 6078T55P10, 6078T55P12, 6078T55P13, 6078T55P14, 6078T55P15, or 6078T55P16 installed, within 30 days after the effective date of this AD, install an MFC with a flange vent groove that conforms to the requirements of CF34 ASB CF34AL S/B 73–0026, dated August 12,1999, or CF34BJ S/B 73–0041, dated August 12, 1999.

Replacement of the MFC

(b) For all CF34–1A, –3A, and –3A2 series engines with SN's 350003 through 350525, install an MFC with a flange groove that conforms to the requirements of CF34 ASB CF34AL S/B 73–0026, dated August 12, 1999, the next time the engine is removed or the next time the MFC is removed.

(c) Install a serviceable MFC with improved overspeed protection as follows:

(1) For all CF34–1A, –3A, and –3A2 series engines, install a serviceable MFC at the next hot section inspection, or within 53 months after the effective date of this AD, whichever occurs first, in accordance with step 2A through step 2G of the Accomplishment Instructions of CF34 ASB No. A73–33, dated November 21, 1997, or Revision 1, dated May 29, 1998.

(2) For CF34–3A1, and –3B series engines installed on Canadair aircraft models CL601 or CL604 (Challenger airplanes), install a serviceable MFC at the next hot section inspection, or within 53 months after the effective date of this AD, whichever occurs first, in accordance with step 2A through step 2G of the Accomplishment Instructions of CF34 ASB No. A73–33, dated November 21, 1997, or Revision 1, dated May 29, 1998.

(3) For CF34–3A1 and –3B1 series engines installed on Canadair aircraft model CL601RJ (Regional Jet airplanes), install a serviceable MFC within 4,000 hours TIS after the effective date of this AD, or within 17 months after the effective date of this AD, whichever occurs first, in accordance with step 2A through step 2G of the Accomplishment Instructions of CF34 ASB No. A73–19, Revision 1, dated February 20, 1998.

Terminating Action

(d) Replacing an MFC with a serviceable MFC, as defined in paragraph (e) of this AD, constitutes terminating action for the requirements of this AD.

Definition of a Serviceable MFC

(e) For the purposes of this AD, a serviceable MFC is defined as any MFC that incorporates the improved overspeed protection modifications, or an MFC that has been reworked to provide the improved overspeed protection as provided by the applicable GE ASB and is not one of the following P/N's 6078T55P02, 6078T55P03, 6078T55P04, 6078T55P05, 6078T55P06, 6078T55P07, 6078T55P08, 6078T55P09, 6078T55P10, 6078T55P12, 6078T55P13, 6078T55P14, 6078T55P15, 6078T55P16, 6047T74P11, 6047T74P12, or 6091T07P02.

Alternative Method of Compliance

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(g) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

Manufacturer Service Bulletins

(h) The inspection shall be done in accordance with the following GE service bulletins:

Document no.	Pages	Revision	Date
CF34AL 73–A0025	All	Original	July 7, 1999.
CF34AL 73–0026	All	Original	August 12,1999.
CF34BJ 73–0040	All	Original	July 7,1999.

Document no.	Pages	Revision	Date
CF34BJ 73–0041	All	Original	August 12,1999.
A73–19	All	1	February 20, 1998.
A73–33	All	Original	November 21, 1997.
A73–33	All	1	May 29, 1998.

Total pages: 27.

(i) The incorporation by reference of GE ASB A73–19, dated February 20, 1998; ASB A73–33, dated November 21, 1997; and ASB A73–33, revision 1, dated May 29, 1998, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 as of July 27, 1999.

Address for Obtaining Referenced Service Bulletins

(j) Copies may be obtained from GEAE Technical Publications, Attention: N. Hanna MZ340M2, 1000 Western Avenue, Lynn, MA 01910; telephone (781) 594–2906, fax (781) 594–0600. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

Effective Date of This AD

(k) This amendment becomes effective on December 6, 1999.

Issued in Burlington, Massachusetts, on November 5, 1999.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 99–29740 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NM–257–AD; Amendment 39–11420; AD 99–23–24]

RIN 2120–AA64

Airworthiness Directives; AlliedSignal, Instrument Landing System Navigation Receivers, as Installed in, but Not Limited to, Airbus Model A300 Series Airplanes and Boeing Model 747–100, –100B, –100B SUD, –200B, –200F, –200C, –300, 747SR, and 747SP Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain instrument landing system (ILS) navigation receivers manufactured by AlliedSignal. This action requires replacement of certain resistors in the ILS navigation receiver with higher ohm resistors and replacement of the nameplate on the receiver with a new nameplate. This amendment is prompted by reports of ILS navigation receivers incorrectly indicating signals from the glideslope ground station during final approach. The actions specified in this AD are intended to ensure the ILS receiver provides the flight crew with accurate glideslope data. Inaccurate glideslope data could result in an approach off the glideslope, and, consequently, a landing short of the runway or a runway overrun.

DATES: Effective December 6, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 6, 1999.

Comments for inclusion in the Rules Docket must be received on or before January 18, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 99–NM–257–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from AlliedSignal Aerospace, Technical Publications, Dept. 65–70, P.O. Box 52170, Phoenix, Arizona 85072–2170. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Jay G. Yi, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1013; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION: The FAA has received reports indicating that, during final approach, instrument landing system (ILS) navigation receivers installed on certain Airbus Model A300 series airplanes have indicated a valid signal from the glideslope ground station, though the ground station was not operating. An absent glideslope signal is normally indicated by the glideslope instrument warning flag on the radio direction magnetic indicator. In these events, the glideslope instrument warning flag moved out of view, indicating to the flight crew that a valid signal had been received from the glideslope ground station. Investigation revealed that the ILS navigation receiver was incorrectly responding to a low-voltage signal from the glideslope ground station to the ILS enable input. The manufacturer of the receiver has determined that certain resistors within the receiver are improperly sized to ensure a correct response to all possible voltage signals. This condition, if not corrected, could result in the ILS navigation receiver providing inaccurate data to the flight crew by falsely indicating a valid signal from the glideslope ground station. The glideslope is the vertical flight path that an airplane is to follow when making an ILS landing. Inaccurate data from the ILS navigation receiver could lead to the airplane making an approach off the glideslope, which could result in a landing short of the runway or a runway overrun.

The affected ILS navigation receiver is installed on, but not limited to, Airbus Model A300 series airplanes and Boeing Model 747–100, –100B, –100B SUD, –200B, –200F, –200C, –300, 747SR, and 747SP series airplanes.

Explanation of Relevant Service Information

The FAA has reviewed and approved Bendix/King Service Bulletin RIA–32A–34–47, Revision 1, dated January 1992, which describes procedures for replacement of three resistors in the ILS navigation receiver with higher ohm resistors. The FAA also has reviewed and approved Bendix/King Service Bulletin RIA–32A–34–48, dated December 1991, which describes procedures for replacement of the nameplate on the receiver with a new nameplate (which, among other things, identifies a new part number) once Bendix/King Service Bulletin RIA–32A–34–47 is accomplished.

Accomplishment of the actions specified in the service bulletins is

intended to adequately address the identified unsafe condition.

Explanation of Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design, this AD is being issued to ensure the ILS receiver provides the flight crew with accurate glideslope data. Inaccurate glideslope data could result in an approach off the glideslope, and, consequently, a landing short of the runway or a runway overrun. This AD requires accomplishment of the actions specified in the service bulletins described previously, except as discussed below.

Differences Between This AD and the Service Bulletin

Operators should note that this AD requires replacement of certain resistors in the ILS navigation receiver with higher ohm resistors and replacement of the nameplate on the receiver with a new nameplate within 6 months after the effective date of this AD. Bendix/King Service Bulletin RIA–32A–34–47 recommends that replacement of the resistors with higher ohm resistors should be accomplished, ''during the next routine maintenance.'' In developing an appropriate compliance time for this action, the FAA considered not only the degree of urgency associated with addressing the subject unsafe condition, but the availability of required parts. The FAA has determined that 6 months represents an appropriate interval of time allowable wherein an ample number of required parts will be available for modification of the U.S. fleet within the compliance period. The FAA also finds that such a compliance time will not adversely affect the safety of the affected airplanes.

Operators also should note that, although Bendix/King Service Bulletin RIA–32A–34–48 states that the new part numbers are intended for Airbus Model A300 series airplanes only, this AD requires new part numbers for components installed on any airplane. The FAA has determined that accurate recordkeeping for components on which the replacement has been accomplished necessitates new part numbers.

Cost Impact

None of the airplanes affected by this action are on the U.S. Register. All airplanes included in the applicability of this rule currently are operated by non-U.S. operators under foreign registry; therefore, they are not directly affected by this AD action. However, the FAA considers that this rule is necessary to ensure that the unsafe condition is addressed in the event that any of these subject airplanes are imported and placed on the U.S. Register in the future.

Should an affected airplane be imported and placed on the U.S. Register in the future, it would require approximately 2 work hours to accomplish the required replacement, at an average labor rate of $60 per work hour. Required parts would cost approximately $55 per airplane. Based on these figures, the cost impact of this AD would be $175 per airplane.

Determination of Rule's Effective Date

Since this AD action does not affect any airplane that is currently on the U.S. register, it has no adverse economic impact and imposes no additional burden on any person. Therefore, prior notice and public procedures hereon are unnecessary and the amendment may be made effective in less than 30 days after publication in the **Federal Register**.

Comments Invited

Although this action is in the form of a final rule and was not preceded by notice and opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 99–NM–257–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

99–23–24 AlliedSignal: Amendment 39–11420. Docket 99–NM–257–AD.

Applicability: RIA–32A instrument landing system (ILS) navigation receivers having part numbers (P/N) 2070724–3201 and 3203; as installed in, but not limited to, Airbus Model A300 series airplanes and Boeing Model 747–100, –100B, –100B SUD, –200B, –200F, –200C, –300, 747SR, and 747SP series airplanes; certificated in any category.

Note 1: This AD applies to AlliedSignal RIA–32A ILS navigation receivers having P/

N 2070724–3201 and –3203, as installed on any airplane, regardless of whether the airplane has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To ensure the ILS receiver provides the flight crew with accurate glideslope data, accomplish the following:

Replacement

(a) For ILS navigation receivers having serial numbers 1 through 2365 inclusive: Within 6 months after the effective date of this AD, replace three resistors in the ILS navigation receiver with higher ohm resistors in accordance with Bendix/King Service Bulletin RIA–32A–34–47, Revision 1, dated January 1992; and replace the nameplate on the receiver with a new nameplate in accordance with Bendix/King Service Bulletin RIA–32A–34–48, dated December 1991.

(b) For ILS navigation receivers having serial numbers 2366 and subsequent: Within 6 months after the effective date of this AD, replace the nameplate on the receiver with a new nameplate in accordance with Bendix/King Service Bulletin RIA–32A–34–48, dated December 1991.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Avionics Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(e) The replacements shall be done in accordance with Bendix/King Service Bulletin RIA–32A–34–47, Revision 1, dated January 1992; and Bendix/King Service Bulletin RIA–32A–34–48, dated December 1991. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from AlliedSignal Aerospace, Technical Publications, Dept. 65–70, P.O. Box 52170, Phoenix, Arizona 85072–2170. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 6, 1999.

Issued in Renton, Washington, on November 5, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–29739 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NM–316–AD; Amendment 39–11421; AD 99–23–25]

RIN 2120–AA64

Airworthiness Directives; Fokker Model F27 Mark 050 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Fokker Model F27 Mark 050 series airplanes. This action requires replacement of the lighting plates of the fuel control panel and the electrical power control panel with new, improved lighting plates. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified in this AD are intended to prevent internal short circuits in the fuel control and electrical power control panels, which could result in burning of the panels and consequent smoke in the flight deck area.

DATES: Effective December 6, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 6, 1999.

Comments for inclusion in the Rules Docket must be received on or before December 20, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 99–NM–316–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Fokker Services B.V., P.O. Box 231, 2150 AE Nieuw-Vennep, the Netherlands. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: The Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, notified the FAA that an unsafe condition may exist on certain Fokker Model F27 Mark 050 series airplanes. The RLD advises that some operators of Fokker Model F27 Mark 050 series airplanes have experienced material stress on the lighting plates of certain electrical power control panels and fuel control panels. These stresses have caused internal short circuits, which in turn resulted in burned spots on the lighting plates. During these incidents, some smoke and odor was evident. This condition, if not corrected, could result in burning of the panels and consequent smoke in the flight deck area.

Explanation of Relevant Service Information

Fokker has issued Component Service Bulletin F7941–005–28–03, dated September 15, 1993, which describes procedures for replacement of the lighting plate of the fuel control panel with an improved lighting plate. Fokker has also issued Component Service Bulletin F7941–011–24–11, dated September 15, 1993, which describes procedures for replacement of the lighting plate of the electrical power control panel with an improved lighting plate. Accomplishment of the actions specified in the service bulletins is intended to adequately address the identified unsafe condition. The RLD classified these service bulletins as mandatory and issued Dutch airworthiness directive 93–141 (A), dated November 1, 1993, in order to assure the continued airworthiness of these airplanes in the Netherlands.

FAA's Conclusions

This airplane model is manufactured in the Netherlands and is type

certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.19) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the RLD has kept the FAA informed of the situation described above. The FAA has examined the findings of the RLD, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to prevent internal short circuits in the fuel control and electrical power control panels, which could result in burning of the panels and consequent smoke in the flight deck area. This AD requires accomplishment of the actions specified in the service bulletins described previously.

Cost Impact

None of the airplanes affected by this action are on the U.S. Register. All airplanes included in the applicability of this rule currently are operated by non-U.S. operators under foreign registry; therefore, they are not directly affected by this AD action. However, the FAA considers that this rule is necessary to ensure that the unsafe condition is addressed in the event that any of these subject airplanes are imported and placed on the U.S. Register in the future.

Should an affected airplane be imported and placed on the U.S. Register in the future, it would require approximately 2 work hours to accomplish the required replacements, at an average labor rate of $60 per work hour. Required parts would cost approximately $1,480 per airplane. Based on these figures, the cost impact of this AD would be $1,600 per airplane.

Determination of Rule's Effective Date

Since this AD action does not affect any airplane that is currently on the U.S. register, it has no adverse economic impact and imposes no additional burden on any person. Therefore, prior notice and public procedures hereon are unnecessary and the amendment may be made effective in less than 30 days after publication in the **Federal Register.**

Comments Invited

Although this action is in the form of a final rule and was not preceded by notice and opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 99–NM–316–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

99–23–25 Fokker Services B.V.: Amendment 39–11421. Docket 99–NM–316–AD.

Applicability: Model F27 Mark 050 series airplanes, serial numbers 20103 through 20231 inclusive, certificated in any category, and equipped with any control panel having a part number (P/N) listed below:

Electrical power control panel P/N:
F7941–011–407
F7941–011–413
F7941–011–425
F7941–011–435
W7981–011–401
W7981–011–403

Fuel control panel P/N:
F7941–005–403
F7941–005–407
F7941–005–409
F7941–005–411
F7941–005–413
F7941–005–415
W7981–005–401

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent internal short circuits in the fuel control and electrical power control panels, which could result in burning of the panels and consequent smoke in the flight deck area, accomplish the following:

Replacement

(a) Within one year after the effective date of this AD: Replace the lighting plate of the fuel control panel with a new, improved plate, in accordance with Fokker Component Service Bulletin F7941–005–28–03, dated September 15, 1993.

(b) Within one year after the effective date of this AD: Replace the lighting plate of the electrical power control panel with a new, improved plate, in accordance with Fokker Component Service Bulletin F7941–011–24–11, dated September 15, 1993.

Spare Parts

(c) As of the effective date of this AD, no person shall install a lighting plate, P/N 95–1847–1, 95–1838–1, or 95–1838–3, on any airplane.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(f) The actions shall be done in accordance with Fokker Component Service Bulletin F7941–005–28–03, dated September 15, 1993, and Fokker Component Service Bulletin F7941–011–24–11, dated September 15, 1993. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Fokker Services B.V., P.O. Box 231, 2150 AE Nieuw-Vennep, the Netherlands. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Dutch airworthiness directive 93–141 (A), dated November 1, 1993.

(g) This amendment becomes effective on December 6, 1999.

Issued in Renton, Washington, on November 5, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–29738 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NM–47–AD; Amendment 39–11416; AD 99–23–20]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737–100, –200, –300, –400, and –500 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 737–100, –200, –300, –400, and –500 series airplanes. For certain airplanes, this AD requires installation of a transient suppression diode in the wiring circuit of the refueling valve-to-float switch of each fuel tank. For certain other airplanes, this AD requires replacement of the existing transient suppression diode with an improved diode. This AD also requires a functional test to verify proper installation of each diode, and corrective action, if necessary. This amendment is prompted by incidents of electrical fire during fueling of the airplane, due to a short circuit and overheating of a transient suppression diode. The actions specified by this AD are intended to prevent such conditions, which could result in electrical arcing and ignition of fuel vapors at the refueling receptacle for the fuel tanks, and consequent fire during airplane fueling.

DATES: Effective December 27, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 27, 1999.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dorr Anderson, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2684; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Boeing Model 737–100, –200, –300, –400, and –500 series airplanes was published in the **Federal Register** on June 14, 1999 (64 FR 31762). That action proposed to require, for certain airplanes, installation of a transient suppression diode in the wiring circuit of the refueling valve-to-float switch of each fuel tank. For certain other airplanes, the proposal would require replacement of the existing transient suppression diode with an improved diode. The proposal also would require a functional test to verify proper installation of each diode, and corrective action, if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Request to Revise Cost Estimate

Two commenters request that the FAA revise the cost estimate and the number of hours required to complete the installation or replacement. One commenter states that the estimated material cost alone, based on Boeing's quoted price for the wire kit, is $800. The other commenter states that the kit price is $1,106. In addition, one commenter estimates that 12 work hours are required to modify an airplane while another commenter estimates that 16 work hours are required to complete the modification. One of the commenters indicates that additional time is required to gain access to the transient suppression diodes, close up the area, and perform functional testing.

The FAA partially concurs. The cost estimate for required parts has been increased to $800 per airplane from $50 per airplane, using the kit price that the commenter states is based upon Boeing's quoted price. The FAA work hour estimate has been increased to 12 work hours from 7 hours based upon information supplied by the commenters. However, the FAA is not

increasing the work hour estimate to account for functional testing since this has already been accounted for in the work hour estimate in the manufacturer's service bulletin. The final rule has been revised to incorporate the above changes in the cost estimate.

Request to Extend Compliance Time

Three commenters request that the compliance period be extended to 18 months from 12 months. Two commenters state that the circuit that includes the transient suppression diode is only powered on the ground during fueling and has no function in the air. One of the commenters also notes that the same circuit is affected by AD 99–05–12, which requires either deactivation of the circuit or installation of double teflon sleeving over the float switch wiring for the center fuel tank to prevent a possible short in the system. A third commenter notes that extending the compliance time to 18 months will allow for diode replacement at the same time as the replacement of the float switch wiring for the center fuel tank (per AD 99–05–12).

Another commenter indicates that extending the compliance period to 18 months will allow for installation or replacement (as applicable) during the next ''C'' check. In addition, this commenter states that the compliance time should be extended to account for the airplane manufacturer's estimate of a 300-day lead time for kits listed in the service bulletin.

The FAA does not concur with the commenters' request to extend the compliance time. The FAA agrees that the circuit which includes the transient suppression diode is powered only on the ground during fueling and has no function in the air. However, this fact does not nullify the safety hazard posed by overheating of the transient suppression diode. During the comment period for the proposed AD, an overheated transient suppression diode caused another fire during fueling. Although the fire was extinguished before extensive damage occurred, the FAA finds that this condition is a significant safety hazard.

With regard to the comment that installation of an improved transient suppression diode should be performed at the same time as modification of wiring for the center tank float switch in accordance with AD 99–05–12, the actions required by the two AD's are performed in different locations on the airplane and do not have a direct bearing on each other. Additionally, the compliance threshold for AD 99–05–12 is 30,000 flight hours. The FAA estimates that there are more than 2,000 airplanes that currently have fewer than 30,000 flight hours, and operators of those airplanes are not required to modify the wiring of the center tank float switch in accordance with AD 99–05–12 until the airplanes have accumulated 30,000 flight hours. The FAA finds that extending the compliance threshold for this AD to 30,000 flight hours, to allow for installation of an improved transient suppression diode at the same time as modification of wiring for the center tank float switch, is inappropriate because it would not address the identified unsafe condition in a timely manner.

The FAA has determined that a 12-month compliance period, as proposed, is warranted. The manufacturer has advised that an ample number of required parts will be available for installation in the U.S. fleet within the compliance period. The manufacturer indicated that the 300-day-lead-time quote was a standard quote for this type of part. However, production schedules have been modified to support this AD. The improved transient suppression diodes are being produced at a rate of 1,500 per month to ensure availability within the 12-month compliance period. In developing an appropriate compliance time for this action, the FAA considered not only the degree of urgency associated the addressing the subject unsafe condition, but the availability of required parts and the practical aspect of installing the required modification within an interval of time that parallels normal scheduled maintenance for the majority of affected operators. No change to the final rule is necessary in this regard.

Request to Develop a New Transient Suppression Diode

One commenter requests that the FAA require the airplane manufacturer to develop a transient suppression diode with better mechanical protection from stresses to prevent possible overheating. The commenter states that the improved transient suppression diode is made of the same components as the existing diode, with essentially the same manufacturing process and the same mechanical protection (heat-shrunk plastic sleeving); only the arrangement of the wiring is different. The commenter states that the lack of significant changes to the design may result in more failures of the improved diodes (due to damage during installation) than if the existing diodes had been left in place.

The FAA does not concur. The manufacturer has made production changes to eliminate the stress conditions which occurred in the existing diode design. Based upon the production changes, the FAA does not anticipate that variation in installation will lead to failures of the improved diode as the commenter suggests. The improved diodes have been used on other Boeing model airplanes. A review of the service history on the improved diodes on other Boeing model airplanes confirms that they do not have a history of failure in service. No change to the final rule is necessary in this regard.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 2,897 airplanes of the affected design in the worldwide fleet. The FAA estimates that 1,126 airplanes of U.S. registry will be affected by this AD.

For all airplanes, it would take approximately 12 work hours per airplane to accomplish the replacement or installation (as applicable) and the functional test to verify proper installation, at an average labor rate of $60 per work hour. Required parts would cost approximately $800 per airplane. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $1,711,520 or $1,520 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under

Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

99–23–20 Boeing: Amendment 39–11416. Docket 99–NM–47–AD.

Applicability: Model 737–100, –200, –300, –400, and –500 series airplanes; line numbers 1 through 3016 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent a short circuit and overheating of the transient suppression diode, which could result in electrical arcing and ignition of fuel vapors at the fueling receptacle for the fuel tanks, and consequent fire during airplane fueling, accomplish the following:

Corrective Action

(a) For Group 1 airplanes, as identified in Boeing Service Bulletin 737–28–1115, dated March 4, 1999: Within 12 months after the effective date of this AD, install a transient suppression diode, part number (P/N) 69–58806–4, in the wire bundle (W264) of the refueling valve-to-float switch of each fuel tank, in accordance with the service bulletin.

(b) For Groups 2, 3, and 4 airplanes, as identified in Boeing Service Bulletin 737–28–1115, dated March 4, 1999: Within 12 months after the effective date of this AD, replace the existing transient suppression diode, P/N 69–58806–1 or 69–58806–3, installed in the wire bundle (W264) of the refueling valve-to-float switch of each fuel tank, with an improved diode, P/N 69–58806–4, in accordance with the service bulletin.

(c) Prior to further flight following accomplishment of the actions required by paragraph (a) or (b) of this AD, perform a functional test to verify proper installation of each diode in accordance with Boeing Service Bulletin 737–28–1115, dated March 4, 1999. If any discrepancy is detected during any functional test, prior to further flight, replace the discrepant diode and repeat the functional test, in accordance with the service bulletin.

Spares Paragraph

(d) As of the effective date of this AD, no person shall install a transient suppression diode having P/N 69–58806–1 or 69–58806–3 on any airplane.

Alternative Methods of Compliance

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(g) The corrective actions shall be done in accordance with Boeing Service Bulletin 737–28–1115, dated March 4, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on December 27, 1999.

Issued in Renton, Washington, on November 4, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–29737 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–ANE–74–AD; Amendment 39–11425; AD 98–24–03 R1]

RIN 2120–AA64

Airworthiness Directives; BMW Rolls-Royce GmbH Models BR700–710A1–10 and BR700–710A2–20 Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment revises an existing airworthiness directive (AD), applicable to BMW Rolls-Royce GmbH (BRR) Models BR700–710A1–10 and BR700–710A2–20 turbofan engines. The existing AD requires initial and repetitive visual inspections of the engine compressor and combustion core fairings (also referred to as the engine core fairings) and fasteners for correct installation and damage, and verification that the engine core fairing fasteners are torqued to a higher torque value. This amendment increases the repetitive inspection interval to 150 hours time-in-service (TIS) following an initial inspection and follow-on inspection at the current 50 hours TIS interval. This amendment also requires an initial inspection and follow-on inspection at a 50 hours TIS interval following any engine core fairing or fastener removal, repair, or replacement. Repair of engine core fairings has been added as an alternate to engine core fairing replacement, and an inspection for loose engine core fairing(s) has been included to verify correct installation on the engine. Finally, this amendment adds a new paragraph in the compliance section allowing the option to incorporate redesigned core engine fairings as the terminating action to the required repetitive inspections. This amendment is prompted by results of repetitive inspections that indicate that the inspection interval can be increased safely, and by introduction of redesigned engine core fairings. The

actions specified by this AD are intended to prevent engine compressor or combustion core fairing detachment and damage to the engine bypass duct, resulting in engine failure and damage to the airplane.

DATES: Effective December 27, 1999.

Comments for inclusion in the Rules Docket must be received on or before December 27, 1999.

The incorporation by reference of BRR Service Bulletin BR700–72–900062, Revision 2, dated November 3, 1998, listed in the regulations was approved by the Director of the Federal Register as of March 11, 1999.

The incorporation by reference of all other publications listed in the regulations is approved by the Director of the Federal Register as of December 27, 1999.

ADDRESSES: Submit comments to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–ANE–74–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: ''9-ane-adcomment@faa.gov''. Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in this AD may be obtained from BMW Rolls-Royce GmbH, Eschenweg 11, D–15827 Dahlewitz, Germany; telephone 011–49–33–7086–1883; fax 011–49–33–7086–3276. This information may be examined at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, 7th Floor, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Keith Mead, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7744, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by revising Airworthiness Directive (AD) 98–24–03, Amendment 39–11050 (64 FR 9056, February 24, 1999), following a priority letter AD issued November 12, 1998, which is applicable to BMW Rolls-Royce GmbH (BRR) Models BR700–710A1–10 and BR700–710A2–20 turbofan engines, was published in the **Federal Register** on August 17, 1999 (64 FR 44666). The action proposed to increase the repetitive inspection interval to 150 hours time-in-service (TIS) following an initial inspection and follow-on inspection at the current 50 hours TIS interval. This action also proposed to require an initial inspection and follow-on inspection at a 50 hours TIS interval following any engine core fairing or fastener removal, repair, or replacement. Repair of engine core fairings would be added as an alternate to engine core fairing replacement, and an inspection for loose engine core fairing(s) would be included to verify correct installation on the engine. That action was prompted by results of repetitive inspections that indicate that the inspection interval can be increased safely. That condition, if not corrected, could result in engine compressor or combustion core fairing detachment and damage to the engine bypass duct, resulting in engine failure and damage to the airplane.

No Comments Received

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public.

Optional Terminating Action

Since publication of the NPRM, BRR has issued Service Bulletin (SB) BR700–72–100900, Revision 1, dated September 10, 1999 which introduces redesigned engine core fairings thereby allowing the option to incorporate this redesigned hardware as the terminating action to the required repetitive inspections. The Luftfahrt-Bundesamt (LBA), the airworthiness authority for Germany, has reviewed and approved the technical contents of this SB.

Difference Between NPRM and Final Rule

Except for the optional terminating action, there is no change between the proposal and this final rule.

Bilateral Airworthiness Agreement

This engine model is manufactured in Germany and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the LBA has kept the FAA informed of the situation described above. The FAA has examined the findings of the LBA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Economic Analysis

There exists no adverse economic impact because this revised rule only increases the repetitive inspection interval. However, if an operator chooses to install the new engine core fairings, the labor is approximately 25 work hours at the average labor rate of $60 per work hour. Required parts are approximately $141,372. The total cost per engine of the new engine core fairings is $142,872. The manufacturer has advised the FAA that they may lower the economic burden on operators by reimbursing the costs associated with the incorporation of the redesigned engine core fairings.

Adoption of the Rule

After careful review of the available data, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously.

Comments Invited

Since the optional terminating action involving installation of new engine core fairings was not in the NPRM, comments are invited from the public on this option and its economic impact. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 98–ANE–74–AD.'' The

postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air Transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Amendment 39–11050 (64 FR 9056, February 24, 1999), and by adding a new airworthiness directive, Amendment 39–11425, to read as follows:

98–24–03 R1 BMW Rolls-Royce GmbH: Amendment 39–11425. Docket 98–ANE–74–AD. Revises AD 98–24–03, Amendment 39–11050.

Applicability: BMW Rolls-Royce GmbH (BRR) Model BR700–710A1–10 and BR700–710A2–20 turbofan engines installed on, but not limited to, Gulfstream Aerospace G–V and Bombardier BD–700–1A10 series airplanes.

Note 1: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent engine compressor and combustion core fairing (also referred to as the engine core fairing) detachment which could result in damage to the engine bypass duct, engine failure and damage to the aircraft, accomplish the following:

Inspections, Repair, Replacement, and Torquing

(a) Prior to further flight, visually inspect the engine core fairings and fasteners to ensure correct installation and for cracks, loose fairings, or fasteners, and if loose, cracked, damaged, or improperly installed, repair or replace with serviceable parts. Torque all the fasteners to the increased torque value, in accordance with BRR Service Bulletin (SB) BR700–72–900062, Revision 1, dated October 29, 1998, or Revision 2, dated November 3, 1998, or Revision 3, dated March 24, 1999.

(b) Thereafter, except as provided in paragraphs (c) or (d) of this AD, at intervals not to exceed 50 hours time-in-service (TIS) since last inspection, visually inspect the engine core fairings and fasteners for cracks, loose fairings, or fasteners, and, if loose, cracked, or damaged, repair or replace with serviceable parts. Torque all the fasteners to the increased torque value, in accordance with BRR SB BR700–72–900062, Revision 2, dated November 3, 1998, or Revision 3, dated March 24, 1999.

(c) Following an initial inspection in accordance with paragraph (a) of this AD, and one follow-on inspection in accordance with paragraph (b), if both inspections found no cracks, damage, loose fairings or fasteners the repetitive inspection interval may be increased to 150 hours TIS since last inspection in accordance with the procedures described in paragraph (b) of this AD.

(d) Reinspection and retorquing prior to further flight is required in accordance with paragraph (a) of this AD, following any engine core fairing or fastener which has been removed, repaired or replaced. One successful follow-on inspection and retorque in accordance with paragraph (b) of this AD must be accomplished before the repetitive 150 hour TIS inspection interval described in paragraph (c) of this AD is permitted.

Optional Terminating Action

(e) Incorporation of the redesigned engine core fairings in accordance with BRR SB BR700–72–100900, Revision 1, dated September 10, 1999, constitutes terminating action for the requirements specified in paragraphs (a), (b), (c), and (d) of this AD.

Alternative Methods of Compliance

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

Incorporation by Reference

(g) The actions required by this AD shall be done in accordance with the following BRR SBs: BR700–72–900062, Revision 1, dated October 29, 1998; Revision 2, dated November 3, 1998; Revision 3, dated March 24, 1999; and BR700–72–100900, Revision 1, dated September 10, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from BMW Rolls-Royce GmbH, Eschenweg 11, D–15827 Dahlewitz, Germany; telephone 011–49–33–7086–1883; fax 011–49–33–7086–3276. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(h) This amendment becomes effective on December 27, 1999.

Issued in Burlington, Massachusetts, on November 5, 1999.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 99–29823 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NM–303–AD; Amendment 39–11426; AD 99–24–02]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200 and –300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is

applicable to certain Boeing Model 767–200 and –300 series airplanes. This action requires a one-time visual inspection to determine the part number and serial number of the lower drag strut of the nose landing gear (NLG); and corrective actions, if necessary. This amendment is prompted by reports of a fracture of the lower drag strut of the NLG, which was caused by a thin wall thickness condition that occurred during the manufacturing process. The actions specified in this AD are intended to prevent a fracture of the lower drag strut, which could result in collapse of the NLG.

DATES: Effective December 6, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 6, 1999.

Comments for inclusion in the Rules Docket must be received on or before January 18, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 99–NM–303–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: James G. Rehrl, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2783; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION: The FAA has received reports of a fracture of the lower drag strut of the nose landing gear (NLG) on certain Boeing 767–200 and –300 series airplanes. Investigation revealed that the fractured lower drag strut of the NLG was found to have been manufactured with a thin wall thickness condition. This condition, if not detected and corrected, could result in a fracture of the lower drag strut and collapse of the NLG.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 767–32A0185, dated September 2, 1999, which describes procedures for a one-time visual inspection to determine the part number and serial number of the lower drag strut of the NLG; and corrective actions, if necessary. The corrective actions involve performing a one-time ultrasonic inspection to measure the thickness of the lower drag strut. The corrective actions also involve either overhauling the lower drag strut if the thickness is within certain limits or replacing the lower drag strut with a new or serviceable lower drag strut, if the thickness is outside certain limits. Accomplishment of the actions specified in the alert service bulletin is intended to adequately address the identified unsafe condition.

Explanation of the Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design, this AD is being issued to prevent a fracture of the lower drag strut, which could result in collapse of the NLG. This AD requires accomplishment of the actions specified in the alert service bulletin described previously.

This AD also requires that operators report all inspection results (positive only) to the FAA.

Determination of Rule's Effective Date

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 99–NM–303–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

99–24–02 Boeing: Amendment 39–11426. Docket 99–NM–303–AD.

Applicability: Model 767–200 and –300 series airplanes, as listed in Boeing Alert Service Bulletin 767–32A0185, dated September 2, 1999; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent a fracture of the lower drag strut, which could result in collapse of the nose landing gear (NLG), accomplish the following:

Visual Inspection

(a) Within 90 days after the effective date of this AD, perform a one-time visual inspection to determine the part number and serial number of the lower drag strut of the NLG, in accordance with Boeing Alert Service Bulletin 767–32A0185, dated September 2, 1999. If the prefix of the serial number of the lower drag strut is not HM or FRG, no further action is required by this AD.

Ultrasonic Inspection

(b) For airplanes on which lower drag strut having part number (P/N) 162T2003–5 and serial number (S/N) prefix HM or FRG is installed: Prior to further flight, perform a one-time ultrasonic inspection to measure the wall thickness of the lower drag strut of the NLG, in accordance with Boeing Alert Service Bulletin 767–32A0185, dated September 2, 1999, and accomplish paragraph (b)(1), (b)(2), or (b)(3) of this AD, as applicable, at the time specified.

(1) If the wall thickness is greater than or equal to 0.210 inch: No further action is required by this AD.

(2) If the wall thickness is greater than or equal to 0.180 inch, but less than 0.210 inch: Within 5 years after the effective date of this AD, overhaul the lower drag strut in accordance with Part 2 of the Accomplishment Instructions of the alert service bulletin.

(3) If the wall thickness is less than 0.180 inch: Prior to further flight, replace the lower drag strut with a new or serviceable lower drag strut in accordance with Part 3 of the Accomplishment Instructions of the alert service bulletin.

(c) For airplanes on which lower drag strut having P/N 162T2003–1 or 162T2003–3 and S/N prefix HM or FRG is installed: Perform a one-time ultrasonic inspection to measure the wall thickness of the lower drag strut of the NLG, in accordance with Boeing Alert Service Bulletin 767–32A0185, dated September 2, 1999, and accomplish paragraph (c)(1), (c)(2), or (c)(3) of this AD, as applicable, at the time specified.

(1) If the wall thickness is greater than or equal to 0.160 inch: No further action is required by this AD.

(2) If the wall thickness is greater than or equal to 0.150 inch, but less than 0.160 inch: Within 5 years after the effective date of this AD, overhaul the lower drag strut in accordance with Part 2 of the Accomplishment Instructions of the alert service bulletin.

(3) If the wall thickness is less than 0.150 inch: Prior to further flight, replace the lower drag strut with a new or serviceable lower drag strut in accordance with Part 3 of the Accomplishment Instructions of the alert service bulletin.

(d) As of the effective date of this AD, no person shall install on any airplane, a lower drag strut of the NLG having P/N 162T2003–1, 162T2003–3, or 162T2003–5, and S/N prefix HM or FRG, unless the part has been inspected to verify proper wall thickness in accordance with this AD.

Reporting Requirement

(e) Submit a report of the inspection findings (positive only, defined as a thin wall thickness condition that requires corrective action) to the Seattle Manufacturing Inspection District Office (MIDO), 2500 East Valley Road, Suite C–2, Renton, Washington 98055–4056; fax (425) 227–1159; at the applicable time specified in paragraph (e)(1) or (e)(2) of this AD. The report must include the airplane serial number; the number of total flight hours and flight cycles on the airplane. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(1) For airplanes on which the applicable inspection required by either paragraph (b) or (c) of this AD is accomplished after the effective date of this AD: Submit the report within 30 days after performing the inspection.

(2) For airplanes on which the applicable inspection required by either paragraph (b) or (c) of this AD has been accomplished prior to the effective date of this AD: Submit the report for the inspection within 30 days after the effective date of this AD.

Alternative Methods of Compliance

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(g) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(h) The actions shall be done in accordance with Boeing Alert Service Bulletin 767–32A0185, dated September 2, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(i) This amendment becomes effective on December 6, 1999.

Issued in Renton, Washington, on November 9, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–29822 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–ANE–69; Amendment 39–11424; AD 98–21–22 R1]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney JT9D Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment revises an existing airworthiness directive (AD), applicable to Pratt & Whitney JT9D series turbofan engines, that currently requires initial and repetitive eddy current inspections (ECI) of 14th and 15th stage high pressure compressor (HPC) disks for cracks, and removal of cracked disks and replacement with

serviceable parts. This amendment revises the definition of a shop visit to make compliance less restrictive, and adds references to a Nondestructive Inspection Procedure attached to applicable service bulletins. This amendment is prompted by feedback from operators saying that the shop visit definition in the current AD made AD compliance unnecessarily restrictive. The actions specified by this AD are intended to prevent 14th and 15th stage HPC disk rupture, which could result in an uncontained engine failure and damage to the airplane.

DATES: Effective January 18, 2000.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 18, 2000.

ADDRESSES: The service information referenced in this AD may be obtained from Pratt & Whitney, Publications Department, Supervisor Technical Publications Distribution, M/S 132–30, 400 Main St., East Hartford, CT 06108; telephone (860) 565–5570. This information may be examined at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tara Goodman, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7130; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by revising airworthiness directive (AD) 98–21–22, Amendment 39–10830 (63 FR 55500, October 16, 1998), which is applicable to Pratt & Whitney (PW) JT9D–59A, –70A, –7Q, –7Q3, and JT9D-7R4 series turbofan engines, was published in the **Federal Register** on March 30, 1999 (64 FR 15137). The proposal would change the definition of a shop visit from what appears in the current AD, ''the induction of an engine into the shop for scheduled maintenance'' to ''a low pressure turbine module removal.'' In addition, the proposal would add references to the Nondestructive Inspection Procedure No. 858 (NDIP–858), dated November 7, 1995, attached to the various versions of the referenced alert service bulletins (ASBs), which was inadvertently omitted from the current AD.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Difference Between Service Documents and AD

One commenter notes that the reinspection interval for the 14th stage disk in the proposal differs from the reinspection interval provided in the applicable service documents. While the proposal provides for reinspection at intervals not to exceed 4,000 cycles-in-service (CIS) since last eddy current inspection (ECI), the ASB calls for reinspection whenever the high pressure compressor is disassembled sufficiently to access the disk, defined as the removal of the low pressure turbine shaft, after accumulating 100 or more cycles since last inspection. The commenter states that this difference creates a conflict between the proposed AD and the service documents.

The Federal Aviation Administration (FAA) does not concur. The proposal would incorporate ASB JT9D–7R4–A72–524 by reference only for the purpose of providing direction on how to perform the inspection and the reject criteria. The proposal contains its own reinspection interval, which would take precedence over any interval contained in the service documents for purposes of complying with the proposed AD. There is no conflict. The FAA views the reinspection interval in the service documents as more conservative than that required by the proposed AD. The proposed AD, however, does not prohibit additional inspections performed in accordance with the interval stated in the service documents. The FAA has determined that the reinspection interval provided in the proposal provides a sufficient level of safety.

Commenter Concurs

One commenter agrees with the proposal as stated.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously.

No Additional Economic Impact

Since this revised rule only changes the definition of the shop visit and adds reference to the NDIP, there is no effect on the economic analysis.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air Transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Amendment 39–10830 (63 FR 55500, October 16, 1998), and by adding a new airworthiness directive, Amendment 39–11424, to read as follows:

98–21–22 R1 Pratt & Whitney: Amendment 39–11424. Docket 95–ANE–69. Revises AD 98–21–22, Amendment 39–10830.

Applicability: Pratt & Whitney (PW) Model JT9D–59A, –70A, –7Q, –7Q3, and JT9D–7R4 series turbofan engines, with the following 14th and 15th stage high pressure compressor (HPC) disks installed: Part Numbers (P/Ns) 5000814–01, 790014, 789914, 790114, 5000815–01, 5000815–021, 704315, 704315–001, 786215, 786215–001, 704314, 789814, and 790214. These

engines are installed on but not limited to Airbus A300 and A310 series aircraft, Boeing 747 and 767 series aircraft, and McDonnell Douglas DC–10 series aircraft.

Note 1: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent 14th and 15th stage HPC disk rupture, which could result in an uncontained engine failure and damage to the airplane, accomplish the following:

Inspections

(a) Inspect 14th stage HPC disks, P/N 5000814–01, in accordance with Nondestructive Inspection Procedure No. 858 (NDIP–858), dated November 7, 1995, attached to PW Alert Service Bulletin (ASB) No. JT9D–7R4–524, dated December 13, 1995, or Revision 1, dated June 26, 1997, as follows:

(1) Perform an initial eddy current inspection (ECI) for cracks as follows:

(i) For disks with 7,000 or more cycles since new (CSN), and 3,000 or more cycles in service (CIS) since last shop visit, on the effective date of this AD, inspect within the next 1,000 CIS after the effective date of this AD, or at the next shop visit, whichever occurs first.

(ii) For disks with 7,000 or more CSN, and less than 3,000 CIS since last shop visit, on the effective date of this AD, inspect within 4,000 CIS since the last shop visit, or at the next shop visit, whichever occurs first.

(iii) For disks with less than 7,000 CSN on the effective date of this AD, inspect at the next shop visit after the effective date of this AD, but before exceeding 4,000 CIS since last shop visit, or 8,000 CSN, whichever occurs later.

(iv) For uninstalled disks on or after the effective date of this AD, inspect prior to installation.

(2) Thereafter, perform ECI for cracks at intervals not to exceed 4,000 CIS since last ECI.

(3) Prior to further flight, remove cracked disks and replace with serviceable parts.

(b) Inspect 14th stage HPC disks, P/Ns 790014, 789914, 790114, and 15th stage HPC disks, P/N's 5000815–01, 5000815–021, 704315, 704315–001, 786215, and 786215–001, in accordance with NDIP–858, dated November 7, 1995, attached to PW ASB No. JT9D–7R4–A72–524, dated December 13, 1995, or Revision 1, dated June 26, 1997, or PW ASB No. A6232, dated December 13, 1995, or Revision 1, dated January 11, 1996, or Revision 2, dated June 26, 1997, as applicable, as follows:

(1) Perform an initial ECI for cracks as follows:

(i) For disks with 6,500 or more CSN, and 3,000 or more CIS since last shop visit, on the effective date of this AD, inspect within the next 1,000 CIS after the effective date of this AD, or at the next shop visit, whichever occurs first.

(ii) For disks with 6,500 or more CSN, and less than 3,000 CIS since last shop visit, on the effective date of this AD, inspect within 4,000 CIS since the last shop visit, or at the next shop visit, whichever occurs first.

(iii) For disks with less than 6,500 CSN on the effective date of this AD, inspect at the next shop visit after the effective date of this AD, but before exceeding 4,000 CIS since last shop visit, or 7,500 CSN, whichever occurs later.

(iv) For uninstalled disks on or after the effective date of this AD, inspect prior to installation.

(2) Thereafter, perform ECI for cracks at intervals not to exceed 4,000 CIS since last ECI.

(3) Prior to further flight, remove cracked disks and replace with serviceable parts.

(c) Inspect 14th stage HPC disks, P/Ns 704314, 789814, and 790214, in accordance with NDIP–858, dated November 7, 1995, attached to PW ASB No. A6232, original issue, dated December 13, 1995, or Revision 1, dated January 11, 1996, or Revision 2, dated June 26, 1997, as follows:

(1) Perform an initial ECI for cracks as follows:

(i) For disks with 2,000 or more CSN, and 2,000 or more CIS since last shop visit, on the effective date of this AD, inspect within the next 1,000 CIS after the effective date of this AD, or at the next shop visit, whichever occurs first.

(ii) For disks with 2,000 or more CSN, and less than 2,000 CIS since last shop visit, on the effective date of this AD, inspect within 3,000 CIS since the last shop visit, or at the next shop visit, whichever occurs first.

(iii) For disks with 2,000 or more CSN, and no previous shop visits, inspect within 3,000 CIS after the effective date of this AD, or at the next shop visit, whichever occurs first.

(iv) For disks with less than 2,000 CSN on the effective date of this AD, inspect at the next shop visit after the effective date of this AD, but before exceeding 5,000 CSN.

(iv) For uninstalled disks on or after the effective date of this AD, inspect prior to installation.

(2) Thereafter, perform ECI for cracks at intervals not to exceed 3,000 CIS since last ECI.

(3) Prior to further flight, remove cracked disks and replace with serviceable parts.

Inspection Report

(d) Within 30 days of inspection, report inspection results on the form labeled ''14th and 15th Stage HPC Disk Inspection Report,'' to Pratt & Whitney Customer Technical Support. The fax number is listed on that form which is attached to PW ASB No. JT9D–7R4–A72–524, Revision 1, dated June 26, 1997, or PW ASB No. A6232, Revision 2, June 26, 1997. Reporting requirements have been approved by the Office of Management and Budget and assigned OMB control number 2120–0056.

Definition

(e) For the purpose of this AD, a shop visit is defined as a low pressure turbine module removal.

Alternative Method of Compliance

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

Ferry Flight

(g) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(h) The actions required by this AD shall be done in accordance with the following Pratt & Whitney service documents:

Document No.	Pages	Revision	Date
ASB No. A6232	1	2	June 26, 1997.
	2	Original	December 13, 1995.
	3,4	1	January 11, 1996.
	5,6	2	June 26, 1997.
	7–10	Original	December 13, 1995.
Total Pages: 10.			
ASB No. JT9D–7R4–A72–524	1	1	June 26, 1997.
	2–5	Original	December 13, 1995.
	6,7	1	June 26, 1997.
	8–11	Original	December 13, 1995.
Total Pages: 11			
NDIP–858	1–33	Original	November 7, 1995.
Total Pages: 33			

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Pratt & Whitney, Publications Department, Supervisor Technical Publications Distribution, M/S 132–30, 400 Main St., East Hartford, CT 06108; telephone (860) 565–5570. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

Effective Date

(i) This amendment becomes effective on January 18, 2000.

Issued in Burlington, Massachusetts, on November 9, 1999.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 99–29826 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NM–05–AD; Amendment 39–11428; AD 99–24–04]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–9–80 Series Airplanes and Model MD–88 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain McDonnell Douglas Model DC–9–80 series airplanes and Model MD–88 airplanes, that requires a one-time visual inspection to determine whether self-aligning nuts are installed at certain locations of the aft pressure bulkhead tee; and corrective actions, if necessary. This amendment is prompted by reports of failures of certain Hi-Lok pin fasteners of the aft pressure bulkhead tee due to installation of non-self-aligning nuts. The actions specified by this AD are intended to prevent failure of certain Hi-Lok pin fasteners and subsequent gouging of the aft pressure bulkhead tee, which could result in fatigue cracking and reduced structural integrity of the airplane.

DATES: Effective December 27, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 27, 1999.

ADDRESSES: The service information referenced in this AD may be obtained from The Boeing Company, Douglas Products Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1–L51 (2–60). This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Carl Fountain, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5222; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model DC–9–80 series airplanes and Model MD–88 airplanes

was published in the **Federal Register** on February 2, 1999 (64 FR 8530). That action proposed to require a one-time visual inspection to determine whether self-aligning nuts are installed at certain locations of the aft pressure bulkhead tee; and corrective actions, if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Support for the Proposal

All commenters support the objectives of the proposal, however, some of the commenters request several changes.

Requests To Extend the Compliance Time

Several commenters request that the proposed compliance time be revised from the proposed 24 months to 48 months.

One of the commenters states that a 48-month compliance time will allow accomplishment of the actions required by the proposed AD ''in conjunction with an extended maintenance visit.'' The commenter also states that no discrepancies were found during inspections of the subject area during accomplishment of Corrosion Prevention and Control Program (CPCP) tasks. Additionally, no discrepancies were found during recent inspections of self-aligning bolts on out-of-service airplanes.

Two commenters state that replacement of the self-aligning nuts and fasteners will require removal of the lavatory or engine. If non-self-aligning nuts are found and both engines must be removed, the commenters state that accomplishment of the replacement within the 24-month proposed compliance time could significantly disrupt aircraft availability.

One commenter points out that the service bulletin recommends a compliance time of at the operator's earliest practical maintenance period. The commenter states that it does not schedule engine or lavatory removal during a 24-month interval maintenance visit. The commenter also states that the fastener failure in the subject area would be detected during inspections accomplished as part of the routine maintenance program. These inspections are generally accomplished at 48-months intervals. Gouges on the tee would be detected during the inspection mandated by AD 96–16–04, amendment 39–9704 (61 FR 39860, July 31, 1996). The commenter states that, due to these thorough inspections that are routinely accomplished on its fleet, it does not believe that the requirements of the proposed AD should be an airworthiness concern.

The FAA partially concurs. The FAA's intent was that the inspection be conducted during a regularly scheduled heavy maintenance visit for the majority of the affected fleet, when the airplanes would be located at a base where special equipment and trained personnel would be readily available, if necessary. Based on the information supplied by the commenters, the FAA now recognizes that 48 months corresponds more closely to the interval representative of most of the affected operators' normal maintenance schedules. Paragraph (a) of the final rule has been revised to reflect a compliance time of 48 months. The FAA does not consider that this extension will adversely affect safety. However, the FAA does not concur with the commenter that the requirements of this AD are not an airworthiness concern. The FAA finds that the requirements of this AD are necessary to address an identified unsafe condition, as discussed in the preamble of the proposed AD.

Request To Reference a Certain Information Notice

One commenter requests that the proposed AD reference McDonnell Douglas Information Notice MD80–53–201 R02, dated October 21, 1998. The FAA concurs. The information notice clarifies information for parts for the SB09530201–7 kit that was inadvertently omitted on Revision 02 of Service Bulletin MD80–53–201, which is utilized in accomplishing the corrective actions required by paragraph (a)(2) of this AD. Therefore, the FAA has revised paragraph (a) of the final rule accordingly.

Request To Reference Earlier Versions of Referenced Service Bulletin

One commenter requests that the FAA allow accomplishment of the proposed requirements in accordance with McDonnell Douglas Service Bulletin MD80–53–201, dated July 6, 1988, and Revision 1, dated March 22, 1991, in addition to Revision 02, dated July 20, 1998. The FAA concurs. The FAA points out that NOTE 2 of the proposed AD, which is retained in the final rule, states ''inspections, and repair of the aft pressure bulkhead tee longeron end fittings prior to the effective date of this AD, in accordance with McDonnell Douglas Service Bulletin MD80–53–201, dated July 6, 1988, or Revision 1, dated March 22, 1991, are considered acceptable for compliance with the actions required by paragraph (a) of this AD.'' Therefore, no change to the final rule is necessary.

Requests To Revise Corrective Action in Paragraph (a)(2) of the Proposal

Two commenters request that paragraph (a)(2) of the proposed AD be revised to read ''if incorrect nuts are installed at longeron fittings 19, 22, and 29, inspect fitting for gouges and repair or replace fitting per service bulletin 53–201.'' The commenters state that at longersons 19, 22, and 29, if non-self-aligning nuts are installed, the longeron end fitting would be gouged and not the tee fitting.

The FAA concurs with the commenters request that paragraph (a)(2) of the final rule be revised to require inspection of the bulkhead tee and/or longeron end fittings for gouges. The FAA's intent, as indicated under the header of ''Explanation of Requirements of Proposed Rule'' in the preamble of the proposed AD, was that ''the proposed AD would require accomplishment of the actions specified in the service bulletin * * *'' Therefore, the FAA has revised paragraph (a)(2) of the final rule to read ''if any nut is determined to be non-self-aligning, prior to further flight, remove the existing nut and perform a one-time visual inspection to detect gouges in the aft pressure bulkhead tee on station Y=1338.000 and longeron end fitting, as applicable, in accordance with the service bulletin.''

Request To Allow Approval of Repairs by Designated Engineering Representative

One commenter requests that the proposed AD be revised to include a provision for approval of repairs for gouges beyond the limits of the referenced service bulletin by a Boeing Designated Engineering Representative (DER) instead of the Manager of the Los Angeles Aircraft Certification Office (ACO). The commenter asserts that this provision will result in a more efficient and timely repair approval process.

The FAA does not concur. While DER's are authorized to determine whether a design or repair method complies with a specific requirement, they are not currently authorized to make the discretionary determination as to what the applicable requirement is. However, the FAA has issued a notice (N 8110.72, dated March 30, 1998), which provides guidance for delegating authority to certain type certificate holder structural DER's to approve alternative methods of compliance for AD-required repairs and modifications of individual airplanes. The FAA is

currently working with Boeing, Douglas Products Division (DPD), to develop the implementation process for delegation of approval of alternative methods of compliance in accordance with that notice. Once this process is implemented, approval authority for alternative methods of compliance can be delegated without revising the AD.

Request To Revise Cost Impact

One commenter requests the FAA revise the Cost Impact paragraph. The commenter states that, while its true that the inspections take one hour, significant additional time will be required for removal of the lavatories, sidewall panels, cargo liners, and other components. The commenter also states that the cost estimate does not reflect the time associated with repairs that may require the removal of the engines, replacement of discrepant fasteners, and inspections required upon fastener removal.

The FAA does not concur. The economic analysis of the AD is limited only to the cost of actions actually required by the rule. It does not consider the costs of ''on condition'' actions, such as repairing a crack if one is detected during a required inspection (''repair, if necessary''). Such ''on-condition'' repair actions would be required to be accomplished—regardless of AD direction—in order to correct an unsafe condition identified in an airplane and to ensure operation of that airplane in an airworthy condition, as required by the Federal Aviation Regulations. In addition, the FAA recognizes that, in accomplishing the requirements of any AD, operators may incur ''incidental'' costs in addition to the ''direct'' costs. The cost analysis in AD rulemaking actions, however, typically does not include incidental costs, such as the time required to gain access and close up; planning time; or time necessitated by other administrative actions. Because incidental costs may vary significantly from operator to operator, they are almost impossible to calculate. Therefore, no change to the final rule is necessary.

Explanation of Change Made to Proposal

The FAA has clarified the inspection requirement contained in the proposed AD. Whereas the proposal specified a visual inspection, the FAA has revised this final rule to clarify that its intent is to require a general visual inspection. Additionally, a note has been added to the final rule to define that inspection.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 1,042 airplanes of the affected design in the worldwide fleet. The FAA estimates that 695 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the inspection required by this AD on U.S. operators is estimated to be $41,700, or $60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

99–24–04 McDonnell Douglas: Amendment 39–11428. Docket 99–NM–05–AD.

Applicability: Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87) series airplanes, and Model MD–88 airplanes; as listed in McDonnell Douglas Service Bulletin MD80–53–201, Revision 02, dated July 20, 1998; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of certain Hi-Lok pin fasteners and subsequent gouging of the aft pressure bulkhead tee, which could result in fatigue cracking and reduced structural integrity of the airplane, accomplish the following:

Inspection

(a) Within 48 months after the effective date of this AD, perform a one-time general visual inspection to determine whether self-aligning nuts are installed at certain locations of the aft pressure bulkhead tee, in accordance with McDonnell Douglas Service Bulletin MD80–53–201, Revision 02, dated July 20, 1998, as revised by Information Notice MD90–53–201 R02, dated October 21, 1998.

Note 2: For the purposes of this AD, a general visual inspection is defined as ''A visual examination of an interior or exterior

area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

(1) If all nuts installed are self-aligning, no further action is required by this AD.

(2) If any nut is determined to be non-self-aligning, prior to further flight, remove the existing nut and perform a one-time visual inspection to detect gouges in the aft pressure bulkhead tee on station Y=1338.000 and longeron end fitting, as applicable, in accordance with the service bulletin.

(i) If no gouge is detected, prior to further flight, install new self-aligning nuts in accordance with the service bulletin.

(ii) If any gouge is detected that is within the repair limits specified in the service bulletin, prior to further flight, repair the gouge and install new self-aligning nuts in accordance with the service bulletin.

(iii) If any gouge is detected that is outside the repair limits specified in the service bulletin, prior to further flight, repair in accordance with a method approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate.

Note 3: Inspections, and repair of the aft pressure bulkhead tee longeron end fittings prior to the effective date of this AD, in accordance with McDonnell Douglas Service Bulletin MD80–53–201, dated July 6, 1988, or Revision 1, dated March 22, 1991, are considered acceptable for compliance with the actions required by paragraph (a) of this AD.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(d) Except as provided by paragraph (a)(2)(iii) of this AD, the actions shall be done in accordance with McDonnell Douglas Service Bulletin MD80–53–201, Revision 02, dated July 20, 1998. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from The Boeing Company, Douglas Products Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1–L51 (2–60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on December 27, 1999.

Issued in Renton, Washington, on November 10, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–30056 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NM–167–AD; Amendment 39–11427; AD 99–24–03]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–11 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes two existing airworthiness directives (AD), applicable to certain McDonnell Douglas Model MD–11 series airplanes, that currently require inspections in the lower center cargo compartment at frame 1681 to verify that a certain bracket and a certain open face nylon clamp were installed to a specific wire bundle support and to detect damage of the subject wire bundle; and corrective actions, if necessary. This amendment requires a similar inspection and corrective actions required by the existing AD's and removes certain airplanes from the applicability of the existing AD's. This amendment also adds a requirement to install a wire assembly support bracket, clamp, and spacer, or revise the wire assembly support bracket and clamp installation; as applicable. This amendment is prompted by an incident in which the insulation blanket in the lower center cargo compartment was found to be burnt due to a missing wiring harness support bracket/clamp on a wire bundle. The actions specified by this AD are intended to prevent sparks, smoke, and possible fire in the lower center cargo compartment.

DATES: Effective December 27, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 27, 1999.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1–L51 (2–60). This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5350; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 99–08–51, amendment 39–11138 (64 FR 22544, April 27, 1999), and AD 99–09–51, amendment 39–11154 (64 FR 23179, April 30, 1999), which are applicable to certain McDonnell Douglas Model MD–11 series airplanes, was published in the **Federal Register** on August 31, 1999 (64 FR 47438). The action proposed to require inspection of the wire assembly, structure, and blankets for evidence of arcing burns and chafing damage under the center cargo compartment floor; installation of protective sleeving on the wire assembly in the area of the frame; and corrective actions, if necessary. For certain airplanes, the action proposed to require installation of a wire assembly support bracket, clamp, and spacer. For certain other airplanes, the action proposal to require revising the wire assembly support bracket and clamp installation.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due

consideration has been given to the single comment received.

The commenter supports the proposed rule.

Conclusion

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

There are approximately 183 airplanes of the affected design in the worldwide fleet. The FAA estimates that 63 airplanes of U.S. registry will be affected by this AD.

It will take approximately 1 work hour to accomplish the inspection, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the inspection required by this AD on U.S. operators is estimated to be $3,780, or $60 per airplane.

It will take approximately 1 work hour to accomplish the modification, at an average labor rate of $60 per work hour. The cost of required parts will be nominal. Based on these figures, the cost impact of the modification required by this AD on U.S. operators is estimated to be $3,780, or $60 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. However, the FAA has been advised that manufacturer warranty remedies are available for some labor costs associated with accomplishing the proposed actions. Therefore, the future economic cost impact of this rule on U.S. operators may be less than the cost impact figures indicated above.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–11138 (64 FR 22544, April 27, 1999), and amendment 39–11154 (64 FR 23179, April 30, 1999), and by adding a new airworthiness directive (AD), amendment 39–11427, to read as follows:

99–24–03 McDonnell Douglas: Amendment 39–11427. Docket 99–NM–167–AD. Supersedes AD 99–08–51, Amendment 39–11138 and AD 99–09–51, Amendment 39–11154.

Applicability: Model MD–11 series airplanes, as listed in McDonnell Douglas Alert Service Bulletin MD11–24A155, dated June 1, 1999; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent sparks, smoke and possible fire in the lower center cargo compartment, accomplish the following:

Phase 1: Inspection and Corrective Actions

(a) Within 30 days after the effective date of this AD, perform an inspection of the wire assembly, structure, and blankets for evidence of arcing burns and chafing damage under the center cargo compartment floor, in accordance with Phase 1 of the Work Instructions of McDonnell Douglas Alert Service Bulletin MD11–24A155, dated June 1, 1999.

(1) Condition 1. If no arcing or chafing damage is detected, prior to further flight, install protective sleeving on the wire assembly in the area of the frame in accordance with the service bulletin.

(2) Condition 2. If any damaged wire, structure, or blanket is detected, prior to further flight, accomplish the actions specified in paragraphs (a)(2)(i), (a)(2)(ii), and (a)(2)(iii) of this AD.

(i) Repair damaged wire and structure in accordance with the service bulletin.

(ii) Repair or replace any damaged blanket with a new blanket, in accordance with Chapter 25 of the Aircraft Maintenance Manual; however, insulation blankets made of metallized polyethyleneteraphthalate (MPET) may not be used.

(iii) Install protective sleeving on the wire assembly in the area of the frame in accordance with the service bulletin.

Note 2: Accomplishment of the actions required by AD 99–08–51, amendment 39–11138, and AD 99–09–51, amendment 39–11154, prior to the effective date of this AD is considered acceptable for compliance with the requirements of paragraph (a) of this AD.

Phase 2: Modification

(b) Within 18 months after the effective date of this AD, accomplish the actions specified in paragraph (b)(1) or (b)(2) of this AD, as applicable, in accordance with Phase 2 of the Work Instructions of McDonnell Douglas Alert Service Bulletin MD11–24A155, dated June 1, 1999.

(1) For airplanes identified as Group 1 in the service bulletin: Install the wire assembly support bracket, clamp, and spacer.

(2) For airplanes identified as Group 2 in the service bulletin: Revise the wire assembly support bracket and clamp installation.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

Special Flight Permits

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(e) Except as provided by paragraph (a)(2)(ii) of this AD, the actions shall be done in accordance with McDonnell Douglas Alert Service Bulletin MD11–24A155, dated June 1, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1–L51 (2–60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 27, 1999.

Issued in Renton, Washington, on November 10, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–30055 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–AAL–21]

Establishment of Class E Airspace; St. Michael, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, correction.

SUMMARY: This action corrects the error in the geographic description of a final rule that was published in the **Federal Register** on October 5, 1999 (64 FR 53889), Airspace Docket 99–AAL–10.

EFFECTIVE DATE: 0901 UTC, December 30, 1999.

FOR FURTHER INFORMATION CONTACT: Robert Durand, Operations Branch, AAL–531, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5898; fax: (907) 271–2850; email: Bob.Durand@faa.gov. Internet address: http://www.alaska.faa.gov/at.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 99–25850, Airspace Docket 99–AAL–10, published on October 5, 1999, (64 FR 53889), established the Class E airspace area at St. Michael, AK. The coordinates for the St. Michael Airport are in error. The latitude for the St. Michael Airport should read ''lat. 63° 29′ 24″ N.'' This action corrects this error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the error for the the Class E airspace, St. Michael, AK, as published in the **Federal Register** October 5, 1999, (FR Document 99–25850), is corrected as follows: On page 53890. Column 2, correct the latitude for the St. Michael Airport to the following: lat. 63° 29′ 24″ N.

* * * * *

Issued in Anchorage, AK, on November 5, 1999.

Willis C. Nelson,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 99–30263 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 29840; Amdt. No. 1961]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference-approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which affected airport is located; or

3. The Flight Inspection Area Office which originated the SIAP.

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, US Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK. 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description on each SIAP is contained in the appropriate FAA Form 8260 and the National Flight Data Center (FDC)/Permanent (P) Notices to Airmen (NOTAM) which are incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation's Regulations (FAR). Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction of charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies

the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAPs. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained in the content of the following FDC/T NOTAMs for each SIAP. The SIAP information in some previously designated FDC/Temporary (FDC/T) NOTAMs is of such duration as to be permanent. With conversion to FDC/P NOTAMs, the respective FDC/T NOTAMs have been canceled.

The FDC/P NOTAMs for the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these chart changes to SIAPs by FDC/P NOTAMs, the TERPS criteria were applied to only these specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in the TERPS. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Navigation (Air).

Issued in Washington, DC, on November 12, 1999.

L. Nicholas Lacey,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—Standard Instrument Approach Procedures

1. The authority citation for part 97 is revised, to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120, 44071; 49 U.S.C. 106(g); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

* * * *Effective Upon Publication*

FDC date	State	City	Airport	FDC No.	SIAP
10/15/99	ID	Idaho Falls	Fanning Field	FDC 9/8141	ILS RWY 20, Amdt 11A...
10/19/99	CA	Long Beach	Long Beach (Daugherty Field)	FDC 9/8213	ILS RWY 30 Amdt 32...
10/19/99	CA	Long Beach	Long Beach (Daugherty Field)	FDC 9/8215	NDB RWY 30 Amdt 9...
10/19/99	CA	Long Beach	Long Beach (Daugherty Field)	FDC 9/8217	VOR or TACAN or GPS RWY 30 Amdt 7...
10/28/99	FL	Key West	Key West Intl	FDC 9/8444	RADAR–1 Amdt 4...
10/28/99	OH	Toledo	Metcalf Field	FDC 9/8434	VOR/DME or GPS RWY 4 Amdt 2...
10/28/99	OH	Toledo	Metcalf Field	FDC 9/8436	VOR RWY 4 Amdt 9...
11/01/99	LA	Monroe	Monroe Regional	FDC 9/8546	VOR/DME RWY 32, Amdt 2... This replaces FDC 9/7949.
11/01/99	MI	Coldwater	Branch County Memorial	FDC 9/8560	VOR or GPS RWY 6 Amdt 4...
11/01/99	TN	Memphis	Memphis Intl	FDC 9/8539	NDB or GPS RWY 9, Amdt 26...
11/02/99	LA	Monroe	Monroe Regional	FDC 9/8592	VOR RWY 4, Amdt 17... This replaces FDC 9/7942.
11/03/99	AL	Dothan	Dothan Regional	FDC 9/8649	LOC BC RWY 14 Amdt 6D...
11/03/99	ND	Fargo	Hector Intl	FDC 9/8639	ILS RWY 35 Amdt 32B... Replaces FDC 9/8209 Intl 99–24.
11/03/99	OK	Ardmore	Ardmore Downtown Executive	FDC 9/8609	VOR or GPS–A, Amdt 13...
11/03/99	OK	Ardmore	Ardmore Muni	FDC 9/8634	VOR–B, Orig...
11/04/99	AL	Dothan	Dothan Regional	FDC 9/8739	VOR or TACAN or GPS–A, Amdt 11C...
11/04/99	AR	Rogers	Rogers Muni-Carter Field	FDC 9/8689	ILS RWY 19, Amdt 2A...
11/04/99	GA	Canton	Cherokee County	FDC 9/8719	NDB RWY 4, Amdt 2A...
11/04/99	IA	Clarinda	Schenck Field	FDC 9/8697	NDB or GPS–A, Amdt 5...
11/04/99	LA	Monroe	Monroe Regional	FDC 9/8691	ILS RWY 4, Amdt 21...
11/04/99	MO	Joplin	Joplin Regional	FDC 9/8708	GPS RWY 36, Orig...
11/04/99	MO	Joplin	Joplin Regional	FDC 9/8710	ILS RWY 13, Amdt 23...
11/04/99	MO	Macon	Macon-Fower Memorial	FDC 9/8722	VOR RWY 2, Amdt 1...
11/04/99	MO	Macon	Macon-Fower Memorial	FDC 9/8724	VOR/DME or GPS RWY 20, Amdt 1...

FDC date	State	City	Airport	FDC No.	SIAP
11/04/99	MO	Macon	Macon-Fower Memorial	FDC 9/8742	GPS RWY 2, Orig...
11/04/99	NC	Greenville	Pitt-Greenville	FDC 9/8711	GPS RWY 20, Orig...
11/04/99	NJ	Caldwell	Essex County	FDC 9/8738	NDB or GPS RWY 22 Amdt 5A...
11/04/99	TX	Beaumont-Port Arthur	Southeast Texas Regional	FDC 9/8716	GPS RWY 16, Orig...
11/05/99	IA	Des Moines	Des Moines Intl	FDC 9/8781	ILS RWY 31R (Cat I, II, III), Amdt 21...
11/05/99	IL	Chicago	Chicago-O'Hare Intl	FDC 9/8777	ILW RWY 27R, Amdt 24A...
11/05/99	ME	Sanford	Sanford Regional	FDC 9/8778	VOR or GPS RWY 7 Amdt 3A... This Notam Replaces FDC 9/8292 Published in TL99–24.
11/05/99	WI	Madison	Dane County Regional-Truax Field	FDC 9/8757	ILS RWY 21 Orig...
11/08/99	GA	Atlanta	The William B. Hartsfield Atlanta Intl ...	FDC 9/8855	ILS RWY 9L Amdt 6...
11/08/99	GA	Atlanta	The William B. Hartsfield Atlanta Intl ...	FDC 9/8856	ILS RWY 27R Amdt 3...

[FR Doc. 99–30265 Filed 11–18–99; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 29839; Amdt. No. 1960]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference-approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located; or

3. The Flight Inspection Area Office which originated the SIAP.

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405)954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Forms 8260–3, 8260–4, and 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (NFDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Navigation (Air).

Issued in Washington, DC, on November 12, 1999.

L. Nicholas Lacey,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instruction Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, 44701; and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 99.33, 97.35 [Amended]

By amending § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

** * * Effective December 2, 1999*

Philadelphia, PA, Philadelphia Intl, ILS RWY 26, Orig
Sparta, TN, Upper Cumberland Regional, SDF RWY 4, Amdt 3, Cancelled
Sparta, TN, Upper Cumberland Regional, ILS RWY 4, Orig
Giddings, TX, Giddings-Lee County, NDB or GPS RWY 17, Amdt 2

** * * Effective December 30, 1999*

Platinum, AK, Platinum, GPS RWY 13, Orig
St Michael, AK, St Michael, GPS RWY 2, Orig
St Michael, AK, St Michael, GPS RWY 20, Orig
Grand Canyon, AZ, Grand Canyon National Park, GPS RWY 3, Orig
Buena Vista, CO, Central Colorado Regional, GPS RWY 33, Orig
Gainesville, FL, Gainesville Regional, VOR or GPS–A, Amdt 10A, Cancelled
Gainesville, FL, Gainesville Regional, VOR/DME RNAV RWY 28, Amdt 5, Cancelled
Louisville, KY, Louisville Intl-Standiford Field, LOC RWY 29, Orig
Pittsfield, MA, Pittsfield Muni, LOC RWY 26, Amdt 6
Pittsfield, MA, Pittsfield Muni, GPS RWY 8, Amdt 1
Pittsfield, MA, Pittsfield Muni, GPS RWY 26, Orig
Farmingdale, NY, Republic, NDB RWY 1, Amdt 14
Farmingdale, NY, Republic, ILS RWY 14, Amdt 7
Farmingdale, NY, Republic, GPS RWY 1, Orig
Farmingdale, NY, Republic, GPS RWY 14, Orig
Farmingdale, NY, Republic, GPS RWY 19, Orig
Astoria, or, Astoria Regional, GPS RWY 8, Orig
Allentown, PA, Lehigh Valley International, VOR/DME RWY 24, Orig
Allentown, PA, Lehigh Valley International, GPS RWY 24, Orig
York, PA, York, NDB RWY 17, Amdt 6
York, PA, York, GPS RWY 17, Amdt 1
York, PA, York, GPS RWY 35, Amdt 2
Carrizo Springs, TX, Dimmit County, NDB RWY 31, Amdt 3
Carrizo Springs, TX, Dimmit County, GPS RWY 31, Orig
Coleman, TX, Coleman Muni, NDB RWY 15, Amdt 2
Coleman, TX, Coleman Muni, GPS RWY 15, Orig
Mineral Wells, TX, Mineral Wells, VOR RWY 31, Amdt 10
Mineral Wells, TX, Mineral Wells, NDB RWY 31, Amdt 2
Mineral Wells, TX, Mineral Wells, GPS RWY 31, Orig
Wallops Island, VA, Wallops Flight Facility, VOR/DME or TACAN RWY 10, Amdt 4
Wallops Island, VA, Wallops Flight Facility, VOR or TACAN or GPS RWY 17, Amdt 6
Madison, WI, Dane County Regional-Truax Field, GPS RWY 21, Orig

The FAA published an Amendment in Docket No. 29814, Amdt. No. 1956 to Part 97 of the Federal Aviation Regulations (Vol 64 No. 206 Page 57560; dated October 26, 1999), under section 97.33 effective December 30, 1999, which is hereby amended as follows:

Brooksville, FL, Hernando County, GPS RWY 2, Orig, should read Brooksville, FL, Hernando County, GPS RWY 3, Orig.
Brooksville, FL, Hernando County, GPS RWY 20, Amdt 1, should read Brooksville, FL, Hernando County, GPS RWY 21, Amdt 1.

The FAA published an Amendment in Docket No. 29786, Amdt. No. 1954 to Part 97 of the Federal Aviation Regulations (Vol 64 No. 206 Pages 57563 and 57564, dated October 26, 1999) under section 97.23, 97.27, and 97.29 is hereby amended by rescinding the following FDC NOTAM's for Wilmington, OH, Airborne Airpark:

FDC 9/7495
FDC 9/7496
FDC 9/7497
FDC 9/7498
FDC 9/7499
FDC 9/7500
FDC 9/7501
FDC 9/7502

[FR Doc. 99–30264 Filed 11–18–99; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 225, 510, 514, 515, and 558

[Docket No. 97N–0276]

RIN 0910–AB18

Animal Drug Availability Act; Medicated Feed Mill Licenses

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing a final rule amending the new animal drug regulations to implement the medicated feed mill licensing requirements of the Animal Drug Availability Act of 1996 (ADAA). The ADAA amended the Federal Food, Drug, and Cosmetic Act (the act) to require that each facility that manufactures feeds containing approved new animal drugs possess a medicated feed mill license for the facility, rather than a separate medicated feed application

(MFA) for each medicated feed manufactured by the facility, as previously required by the act. The final rule implements the feed mill licensing provisions of the ADAA.

EFFECTIVE DATE: December 20, 1999

FOR FURTHER INFORMATION CONTACT: William D. Price, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6652.

SUPPLEMENTARY INFORMATION:

I. Background

The ADAA (Public Law 104–250), which amended sections 512(a) and (m) of the act (21 U.S.C. 360b(a) and (m)), replaces the system that required the agency's approval for the manufacture of specific medicated feeds with a site licensing system for the manufacture of such feeds.

Prior to the passage of the ADAA, an approved MFA was required by the act for the manufacture of medicated feed. The act required a feed mill (referred to also as ''feed manufacturer,'' ''feed firm,'' or ''feed manufacturing facility'') to submit a separate MFA for each medicated feed manufactured by the firm. The ADAA eliminates this requirement and provides for feed mills to be licensed and allows licensed facilities to manufacture any feed containing an approved new animal drug. Additionally, section 512(m)(6) of the act, as added by the ADAA, provides the agency with the authority, to the extent consistent with the public health, to exempt facilities that manufacture certain types of medicated feed from the requirement of obtaining a medicated feed mill license.

These final regulations implementing section 512(m) of the act as amended by the ADAA require only one facility license for the manufacture of animal feeds containing approved new animal drugs, instead of multiple approved MFA's. Furthermore, those medicated feeds previously exempted from the MFA requirement under § 558.4 (21 CFR 558.4) will also be exempt from the requirement of being manufactured in a licensed feed mill under this regulation.

The ADAA also provided for a transitional license for any feed manufacturing facility that, at the time of enactment of the ADAA, held an approved MFA for the manufacture of a medicated feed . Transitional licenses expired April 9, 1998. The Office of Management and Budget (OMB) approved the paperwork requirements for licensing for a 3-year period on October 31, 1997 (OMB control number 0910–0337).

II. Summary of the Proposed Rule

In the **Federal Register** of July 30, 1997 (62 FR 40765), FDA published a proposed rule to implement the feed mill licensing provisions of the ADAA. The proposed rule would add a new part 515 to provide the requirements for medicated feed mill licensing. The proposed rule also would amend part 514 (21 CFR part 514) to remove the provisions regarding MFA's.

The proposed rule set forth the information to be included in medicated feed mill license applications and supplemental applications. The proposed rule also set forth the criteria for, among other things, the approval and refusal to approve a medicated feed mill license application, as well as the criteria for the revocation and/or suspension of a license.

The proposed rule provided conforming amendments to the Code of Federal Regulations (CFR) by removing references to ''MFA's'' and inserting appropriate references to ''medicated feed mill licenses.'' Furthermore, the proposed rule clarified that the scope of the exemption from the requirement of establishment registration is identical to the scope of the exemption from the requirement of a medicated feed mill license. Finally, the proposed rule maintained the general scheme for categories and types of medicated feeds, and provided that those feeds exempted from the MFA requirement now would be exempt from being required to be manufactured in a licensed feed mill.

III. Discussion of Comments

A total of six parties submitted comments to the proposed rule. A discussion of the comments and FDA's responses follows:

A. Possession of Current Approved Labeling

1. Four comments objected to the requirement in proposed § 515.10(b)(6) that the license applicant commit to possess current approved Type B and/or Type C medicated feed labeling for each animal feed containing an approved new animal drug prior to receiving the Type A medicated article containing such drug. Furthermore, these comments objected to the related requirement in proposed § 510.305(b) (21 CFR 510.305(b)) that the medicated feed mill licensee maintain copies of approved labeling at the feed manufacturing facility for those Type B and/or Type C medicated feeds being manufactured. Two comments maintained that the possession by the feed manufacturer of labeling for the Type A medicated article, instead of the Type B and Type C medicated feed labeling, would satisfy the feed labeling requirements of the statute.

These four comments argued that the two proposed provisions, §§ 515.10(b)(6) and 510.305(b), would impose impractical requirements on feed mills, because the mills would be required to possess multiple feed labels for the use of each Type A medicated article before receipt of the Type A medicated article. These comments explained that because many Type A medicated articles may be used in multiple types of approved feeds, feed manufacturers typically do not know at the time of shipment of the Type A medicated article which feeds will be manufactured with the drug. Thus, these comments argued that the only way to satisfy the proposed rule's labeling requirement would be for the drug sponsor to ship in advance to the feed manufacturer the current approved labeling for all possible feeds that could be manufactured with each drug, and then for the feed manufacturer to maintain all of this labeling. The comments concluded that such a practice would pose a significant burden for both the drug sponsor and the feed manufacturer.

FDA has evaluated the comments and has concluded that the act, as amended by the ADAA, requires the licensed feed manufacturing facility to possess and maintain the current approved labeling for those Type B and/or Type C medicated feeds that will be manufactured at that facility prior to receiving the Type A medicated article(s) for these feeds. Section 512(a)(1) of the act, explicitly provides that at the time of removal of a Type A medicated article from a manufacturing, packing, or distributing establishment that the establishment have an unrevoked written statement from the licensed feed manufacturing facility, or a notice from the Secretary of Health and Human Services (the Secretary), that the facility has a medicated feed mill license and current approved labeling for the use of the Type A medicated article in animal feed. Section 512(a)(1) of the act provides that, in the absence of meeting these requirements, the new animal drug is deemed unsafe. A new animal drug deemed unsafe under section 512(a)(1) of the act is adulterated under section 501(a)(5) of the act (21 U.S.C. 351(a)(5)). Thus, the requirement in these regulations that the feed mill possess the current approved labeling is mandated by section 512(a)(1) of the act as amended by the ADAA.

Furthermore, FDA has concluded that the ''approved labeling'' required by the

act and these regulations is that labeling submitted with and approved in the new animal drug application (NADA) for use of the feed containing the new animal drug (the ''Blue Bird'' label), not the labeling for the Type A medicated article as maintained by some comments.

Section 512(b)(1)(F) of the act requires an NADA for a new animal drug intended for use in animal feed to include ''proposed labeling appropriate for such use'' in animal feed as well as specimens of labeling for the drug itself. The regulations at § 514.1(b)(3)(v)(*a*) and (b)(3)(v)(*b*), which implement this provision, specifically require two sets of labels for new animal drugs for use in medicated feeds: ''labeling to be used for such new animal drug with adequate directions for the manufacture and use of finished feeds'' and ''representative labeling proposed to be used for Type B and Type C medicated feeds containing the new animal drug.'' FDA refers to the representative labeling for the Type B and Type C medicated feeds as the ''Blue Bird'' label. This labeling is approved as part of the NADA. FDA believes that Congress intended feed mills to possess and maintain the labeling for use of the feed approved as part of the NADA since this provides the same level of public health protection that existed under the pre-ADAA system under which FDA approved the feed use labeling as part of the MFA and required such labeling to be maintained at the facility. Both systems ensure that each facility has the pertinent information to generate an actual feed label that is consistent with representative medicated feed labeling already approved by the agency.

The agency has concluded that the requirement that licensed feed manufacturers possess Blue Bird labeling for each medicated feed to be manufactured will not add a significant regulatory burden for industry. First, feed manufacturers have possessed and maintained feed labeling approved by FDA since the implementation of the new animal drug regulations in 1971 (36 FR 18375, September 14, 1971). Section 512(m)(1)(d) of the act and the regulations at § 514.2(b)(11) previously required feed manufacturers to submit for FDA's approval the proposed feed labeling with the MFA. Section 512(a)(1) of the act and the regulations at § 510.7 (21 CFR 510.7) also required the feed manufacturer to possess the approved MFA, with the feed labeling, prior to shipment of the Type A medicated article for each feed. Furthermore, the regulations at § 510.305 previously required feed manufacturers to maintain the MFA, with the approved labeling, on site at the facility. Thus, this final rule's requirement that feed mill licensees possess and maintain feed labeling approved by FDA in the NADA (the Blue Bird label), as required by section 512(a) (1) of the act, is in essence the same as the feed manufacturer's previous legal obligation under the act to possess and maintain feed labeling approved by FDA.

Second, drug sponsors have submitted Blue Bird labels with the NADA as required by § 514.1(b)(3)(v)(*b*) (formerly § 135.4a(b)(3)(v)(*b*) (21 CFR 135.4a(b)(3)(v)(b))) since the implementation of the new animal drug regulations in 1971 (36 FR 18375, September 14, 1971.) The requirement for the submission and approval of such labels with the NADA has ensured that these labels are available for distribution to feed manufacturers. Type A manufacturers, in turn, have been supplying approved Blue Bird labels to feed manufacturers since the development of these labels.

Third, feed manufacturers have been using Blue Bird labels as a model to generate actual feed labels and previously used such labels to satisfy the requirement for the submission of representative feed labeling with the MFA. Prior to this final rule, the new animal drug regulations required feed manufacturers to submit an MFA for each medicated feed with ''a copy of the final printed labeling,'' for approval by the agency (§ 135.4b(d); 36 FR 18375, September 14, 1971). Initially, FDA had accepted from the feed manufacturer only the actual feed label to satisfy this requirement. However, an FDA medicated feed task force, after consulting with the Animal Health Institute (AHI), the American Feed Industry Association (AFIA), and the Association of American Feed Control Officials (AAFCO), issued a report in December 1978 that recommended, among other things, that FDA accept ''generic'' labels with the MFA (Ref. 1). Soon after issuance of the task force's report, FDA allowed feed manufacturers to submit the Blue Bird label, rather than the actual feed label, with the MFA. The agency amended § 514.2(b)(11) to allow ''labeling representative of each intended use as stated in the claim'' to be submitted with the MFA (51 FR 7382, March 3, 1986).

FDA has found that since approximately 1980, feed manufacturers have generally relied on the Blue Bird label in submitting the required labeling with the MFA. Feed manufacturers typically submitted with the MFA either a copy of the Blue Bird label or a label derived from the Blue Bird label (an equivalent Blue Bird label). An equivalent Blue Bird label listed the same active drug(s), claim(s), caution and/or warning statements, and mixing and feeding directions as listed in the Blue Bird label. The facility could then generate the actual feed label based on that labeling approved in the MFA. Since the equivalent Blue Bird label was approved as part of the MFA, the agency was assured that the labeling upon which the actual feed label was based correctly reflected the approval conditions of use for the feed.

As noted previously, Type A medicated article manufacturers frequently supplied the appropriate Blue Bird labels to the feed manufacturer for submission with the MFA. Thus, the requirement that the licensed feed manufacturer possess Blue Bird labeling for the feed being manufactured is consistent with industry practice.

FDA agrees with the comments that proposed § 515.10(b)(6) appeared to require a licensed feed mill to commit to possess approved labeling for all possible feeds that could be manufactured from the Type A medicated article. FDA does not intend that a licensed feed manufacturing facility must possess current approved labeling for Type B and/or Type C medicated feeds that the facility does not actually manufacture from the Type A medicated article. Thus, FDA is amending proposed § 515.10(b)(6) (in the final rule, § 515.10(b)(7)) to read, ''A commitment that current approved Type B and/or Type C medicated feed labeling for each Type B and/or Type C medicated feed to be manufactured will be in the possession of the feed manufacturing facility prior to receiving the Type A medicated article containing such drug.''

FDA notes that a feed manufacturer can satisfy the requirement to possess the current approved labeling by maintaining the Blue Bird labeling for each feed to be manufactured at the facility in either paper or electronic format. To assist drug sponsors and feed manufacturers in the distribution of Blue Bird labels and to allow parties to determine more easily whether a feed mill is licensed, FDA has created a data base of medicated feed mill licensing information, available to the public on the Center for Veterinary Medicine's (CVM's) web site at ''http://www.fda.gov/cvm''.

2. One comment argued that proposed §§ 510.305(b) and 515.10(b)(6) should not apply to medicated feed mill licensees because the majority of such licensees are firms with multiple

facilities, where labeling is not created at the feed facility but in the home office. The comment claimed that these firms use the published regulation of approval as the source of required information for the label. Furthermore, the comment argued that the proposed regulation would require such multiple facility firms to distribute Blue Bird labels from the home office to all of the facilities before obtaining the drug, which would serve no purpose. The comment noted that the proposed rule does not apply to nonlicensed facilities and stated that most of these facilities are single mill firms that may not have access to the labeling information in the **Federal Register**, CFR, Feed Additive Compendium, or to a computer with the capability to obtain this information free from the various information sources on the Internet. The comment concluded that the proposed rule's requirement for the possession of Blue Bird labeling should be eliminated, because ''[t]he present system of label development has worked well for the feed industry.''

FDA has considered the previous comment and has concluded that the requirement that licensed feed mills possess Blue Bird labels will not add to the legal obligations with respect to feed labeling that existed for these mills prior to the enactment of ADAA. As discussed previously, before enactment of the ADAA, in accordance with section 512(m)(1)(D) of the act, feed firms submitted with the MFA the specimen of labeling to be approved for that feed. To satisfy this requirement firms typically chose to submit the Blue Bird label as the labeling specimen. Once FDA approved the MFA, the feed mill maintained a copy of the approved MFA, which included the approved labeling, under § 510.305. To comply with the conditions set forth in the MFA for the manufacture of feed, the facility could then generate the actual feed label based on the approved labeling.

Under this rule implementing medicated feed mill licensing, firms that were previously required to have an approved MFA are now required to have a medicated feed mill license and the approved labeling for the manufacture of such feed. Just as the previous regulatory scheme required firms to possess labeling approved by FDA with the MFA for each feed to be manufactured, § 515.10(b)(7) of this rule requires firms to possess the approved labeling for such feed. The only distinction is that instead of the firm maintaining labeling for the feed that is approved by FDA in the medicated feed application process in addition to the NADA approval process, the firm will maintain the Blue Bird medicated feed labeling approved in the NADA. Additionally, § 510.305(b), as revised by this rule, requires that licensed firms maintain the approved labeling on the premises, which is consistent with the previous requirement for maintaining the MFA with a sample of the approved labeling. Thus, the requirements of this rule do not change the previous legal obligations of feed mills to possess and maintain approved labeling for the feed. Furthermore, as also discussed earlier in this preamble, since feed mills previously submitted the Blue Bird label or its equivalent for approval of an MFA, the requirements of this rule are consistent with the industry's method of feed label development.

For those firms where labeling is created based on the CFR or other sources, FDA has concluded that a firm must possess and maintain the Blue Bird label to satisfy the requirements of section 512(a)(1) of the act, and §§ 515.10(b)(6) and 510.305(b) of this final rule. As discussed earlier in the preamble, the statutory requirement that licensed feed mills possess and maintain approved labeling for the feed ensures that these facilities rely on approved labeling to develop the actual feed labels. FDA is revising § 510.305 to clarify that if the home office of a multiple facility firm generates the actual feed labels and maintains the Blue Bird labels for all the feed the multiple facilities manufactures, then only the home office will be required to maintain the Blue Bird labels.

Finally, as for nonlicensed feed mills, such firms are not the subject of this regulation. Feed mills previously exempted from MFA's are also exempt from the licensing requirements set forth in this regulation. FDA previously exempted firms from the requirement that an MFA be approved for the manufacture of Type B and/or Type C medicated feed from Category I Type A medicated articles or from Category II Type B and/or Type C medicated feed, unless otherwise required by regulation. FDA exempted the manufacture of these feeds from the MFA requirements, including the submission of the labeling specimen, because any errors in the manufacture or labeling of such feeds would be unlikely to produce unsafe residues (§ 558.4(a); 51 FR 7382, March 3, 1986). Because nonlicensed facilities can manufacture only exempt feeds, FDA is not proposing that the requirements of §§ 510.305(b) and 515.10(b)(7) in the final rule apply to nonlicensed feed mills.

3. One comment argued that proposed § 510.305 should be amended so that a feed manufacturing firm with multiple establishments can maintain each license at its home office, while the firm simply maintains a ''single readable document with relevant licensing information at each facility.'' Under § 510.305(d), as proposed, the home office of a multiple facility establishment can maintain the original licenses, but each facility must maintain a copy of the license. The license lists the requirements and commitments for the establishment, and it is very important that the people at the manufacturing site understand these requirements. Hence, it is very important that a copy of the license is maintained at each manufacturing facility. Thus, FDA has not changed § 510.305 as requested by the comment.

4. One comment requested that the agency hold a public meeting to discuss alternatives to the proposed rule regarding medicated feed labeling. The comment reasoned that such a meeting would give the agency the opportunity to hear and consider current industry methods and sources for developing labeling for medicated feeds. The comment stated that alternatively, interested members of the public could hold a round table for agency officials to provide the agency with input from industry compliance directors on the development of labeling.

In response to this comment, FDA participated in a meeting with representatives of AFIA and AHI on March 17, 1998. AFIA and AHI presented their views, previously expressed in their written comments, regarding the feed labeling provisions of the medicated feed mill licensing proposed rule. The meeting helped the agency to understand the concerns of industry. Minutes of the meeting are included in Docket No. 97N–0276, and may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

B. Establishment Registration

5. One comment proposed that feed manufacturing facilities be exempt from the annual establishment registration requirement set forth in § 207.20 (21 CFR 207.20), so that all feed mills would be listed as exempt from this requirement under § 207.10 (21 CFR 207.10). The comment argued that establishment registration serves no purpose. The comment stated that one argument for establishment registration is that such registration is required yearly, and provides the agency with a list of who is registered and their locations. However, according to the comment, establishment registration has

not achieved this goal in practice because neither CVM nor field enforcement offices have been provided numbers or locations of establishment registration facilities. The comment argued that, in any case, such information could be updated based on the agency's inspections of firms and the requests by firms for the withdrawal of medicated feed mill licenses.

The comment requests amendments to the registration requirements that are beyond the scope of this rulemaking. FDA is issuing these regulations to provide for medicated feed mill licensing in accordance with the ADAA. Therefore, FDA is not making any substantive changes to the scope of the registration exemption. With regard to the exemptions in § 207.10, FDA is amending the regulation merely to clarify, but not change, the scope of the registration exemption for medicated feed mill licensees. Furthermore, FDA is amending §§ 207.20 and 207.21 (21 CFR 207.21) in the regulations only to replace the phrase ''medicated feed application'' with the term ''medicated feed mill license application.''

Additionally, contrary to the comment's assertion, registration provides beneficial information to the agency that is not available from medicated feed mill licensing. Registration, unlike medicated feed mill licensing, is required annually by 21 CFR 207.22. FDA has found that firms comply with this requirement and provide annually the numbers and locations of registered facilities. This requirement allows FDA to determine which feed mills are still doing or intend to do business. Therefore, the agency believes the exemptions from registration should not be expanded.

C. Ninety-Day Approval Period

6. One comment noted that proposed § 515.20 provides the agency 90 days to act upon a medicated feed mill license application. The comment further noted that the agency did not require the 90 days set forth by regulation to process medicated feed applications, but instead the agency provided the industry timely approvals that ensured that facilities were not placed at a competitive disadvantage. Thus, the comment concluded that 30 days would better reflect the time requirements for acting on a medicated feed mill license application, particularly because a medicated feed mill license approval does not involve the agency's review of the medicated feed labeling.

FDA rejects the suggestion that proposed § 515.20 be changed to allow the agency only 30 days to act on a medicated feed mill license application. First, section 512(m)(2) of the act sets forth explicitly the time limit of 90 days for agency action. Second, almost all feed mills applying for a license will require a preapproval inspection by FDA conducted after filing of the medicated feed mill license application, and it would not be feasible for FDA, in all cases, to conduct the preapproval inspection within 30 days of filing of the application. Of course, as with MFA's, FDA will continue to act as expeditiously as possible in processing license applications.

D. Requirements for Drug Sponsors

7. Three comments noted that the agency accidentally omitted a revision of § 510.7 (21 CFR 510.7) (consignees of new animal drugs for use in the manufacture of animal feeds) in the licensing proposal. The comments suggested that the reference in § 510.7(a)(1) to ''§ 514.2'' should be changed to ''§ 515.10.'' The comments stated that such a change would be consistent with the deletion of § 514.2 (applications for animal feeds bearing or containing new animal drugs) and the establishment of § 515.10 (applications for licenses to manufacture animal feeds bearing or containing new animal drugs).

FDA agrees that in order to be consistent with § 515.10 of these regulations, the reference should be changed as noted in the comments. Furthermore, in order to be consistent with the language of the ADAA, FDA has concluded that § 510.7 must also clarify that at the time of a new animal drug's removal from the establishment of a manufacturer, packer, or distributor of a Type A medicated article, such manufacturer, packer, or distributor must possess an unrevoked written statement from the consignee, or notice from the Secretary, that the consignee holds a medicated feed mill license and has in its possession current approved labeling for the drug in animal feed. Thus, § 510.7(a)(1) has been amended to read as follows: ''Holds a license issued under § 515.20''.

A drug sponsor can satisfy this requirement by receiving written confirmation from the facility as to its feed mill license number or by verifying the feed mill's license status on CVM's web site. The confirmation and/or identification of a feed manufacturing facility's license number indicates that the firm should possess current approved labeling, because the firm must commit to the possession of such labeling in the medicated feed mill license application. The drug sponsor's verification from the FDA web site of an approved facility's license number would constitute ''notice from the Secretary'' that the feed mill possesses a license and the current approved feed labeling. Section 510.7(a)(2) has also been amended to reference the new § 515.10 regulation. As provided in section 512(a)(1)(B)(ii) of the act, if the consignee is not the user of the drug the shipper must obtain an unrevoked written statement from the consignee that the consignee will ship such drug only to a holder of an approved application under § 515.10 of this chapter.

E. Status of Related Citizen Petitions

8. One comment expressed disappointment and concern that the agency was unable to resolve pending issues in order to publish proposed rules for two citizen petitions on drug assays (Docket No. 95P–0373) and on medicated liquid feeds (Docket No. 93P–0174) as part of this rulemaking. The comment further stated that these two petitions suggest significant and appropriate changes to the current good manufacturing practices (CGMP's) and would have saved the agency much time and resources if the agency had published responses concurrently or incorporated such responses in the published proposal on medicated feed mill licenses. The comment stated that the medicated liquid feed petition is long overdue for rulemaking as the agency provided a letter to AFIA on April 19, 1995, that essentially agreed with the substance of AFIA's petition and indicated that a proposal to amend 21 CFR 558.5 was being prepared at that time. The comment urged the agency to act on these two petitions and publish proposed rules to resolve these impasses on serious issues related to the regulation of medicated feed.

FDA is well aware of the two citizen petitions and is actively reviewing these petitions. In preparing this proposal, FDA concluded that incorporating any amendments to the regulations based on these petitions would have unduly delayed the publication of this final rule. The agency plans to develop proposed rules related to these citizen petitions following publication of this final rule.

FDA notes that in a March 30, 1998, amendment to the AFIA and AHI 1995 Citizen Petition (Docket No. 95P–0373) AFIA and AHI withdrew their request to amend § 510.301 (21 CFR 510.301). However, following publication of this final rule FDA intends to develop a proposed rule to amend § 510.301 to be consistent with the requirements of the ADAA.

F. Enforcement Policy

9. One comment requested that the agency take swift and positive compliance action against those firms found to be in violation of CGMP's. FDA recognizes that a visible and firm regulatory posture is essential so that medicated feeds are manufactured, labeled, and distributed in a safe manner. FDA is prepared to take the necessary steps to ensure the safe and effective use of animal drugs in animal feeds.

IV. Additional Changes

FDA has reordered and rewritten subpart A of part 15 to make it more logical and consistent.

V. Environmental Impact

FDA has carefully considered the potential environmental impacts of this rule. The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Medicated feed mill licensing is a procedure established by the ADAA as a replacement for FDA's previous MFA system. The final rule substitutes a facility licensing program for a system of feed-by-feed approval to manufacture feeds containing approved new animal drugs, thereby substantially reducing the number of approval requests required from facilities manufacturing feeds containing new animal drugs. A medicated feed mill license authorizes a feed mill to manufacture any feed containing an approved new animal drug. Previously, a feed mill was required to submit an MFA to manufacture each applicable feed containing an approved new animal drug.

This streamlining does not reduce the responsibility of each facility to manufacture medicated feeds in full compliance with CGMP's regulations. Additionally, the final rule does not prevent FDA from inspecting facilities and their records or taking actions to bring facilities into compliance.

The licensing of a feed mill by FDA does not reduce or change the responsibilities of the mill management to comply with requirements of other Federal, State, or local workplace waste management and emissions laws and regulations. Consistent failure of a facility to comply with hazard communication requirements, to provide necessary worker protection, or to adequately manage wastes could be regarded by FDA as an indication that the facility has a systemic problem that calls into question the ability of the feed mill to comply with FDA CGMP's regulations.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

Under the Regulatory Flexibility Act, unless an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100 or more (adjusted annually for inflation) million in any one year.

The agency has reviewed this final rule and has determined that the rule is consistent with the principles set forth in the Executive Order and in these two statutes. FDA believes that the rule is consistent with the regulatory philosophy and principles identified in the Executive Order and will not have a significant effect on a substantial number of small entities. The Office of Management and Budget has determined that this final rule is a significant regulatory action subject to review under the Executive Order. Also, since the expenditures required by the rule are under $100 million, FDA is not required to perform a cost/benefit analysis according to the Unfunded Mandates Reform Act.

With this rule, FDA is streamlining existing paperwork requirements by amending the process for obtaining approval to manufacture medicated feeds. Instead of requiring an MFA for each applicable medicated feed, this final regulation requires only a single facility license per feed mill, as appropriate. The ADAA granted a transitional license, valid for 18 months, to all feed manufacturing facilities that held an approved MFA. During this time, the facilities could obtain a permanent license by submitting a license application and a copy of an approved MFA to FDA. All other existing reporting responsibilities for each drug remain unchanged.

In its analysis for the proposed rule, the agency had assumed that the only costs to be incurred by industry would be the paperwork costs associated with applying for a facility license. FDA estimated that approximately 2,000 feed mills would be affected by this rule, and that it would take approximately 15 minutes for each facility to complete its application. Taking 1995 median weekly earnings of $684 (Ref. 2) for the executives, administrators, and managers who would complete the applications, and adding 40 percent for fringe benefits, yielded average hourly earnings of $23.94. Thus, the agency estimated a combined paperwork cost for all facilities totaling $11,970 for the first year, and $600 for the estimated 100 mills expected to apply for licensing in each subsequent year. In addition, FDA estimated annual costs of $530 for all of those facilities completing paperwork in reference to license supplements, the voluntary revocation of their license, or hearing procedures. The total cost equaled approximately $6 per mill.

FDA has inflated these costs in the final rule to account for the increase in employment costs from 1995 to 1999. Using the average annual increase of 3.35 percent from 1995 to 1998 over the 4 years from 1995 to 1999, FDA estimates that the combined paperwork costs would total $13,735 in the first year and about $700 in each subsequent year (Ref. 3). Further, paperwork costs in reference to license supplements, voluntary revocation of licenses and hearing procedures would amount to about $600 annually.

Several comments to the proposed rule indicated that additional costs would be incurred due to the labeling requirements of the rule. The agency acknowledges that the costs for feed mills maintaining and retrieving Blue Bird labels was not estimated in the proposal. In Table 3 of section VIII of this document, a total cost to the industry of 500 hours is estimated for a total of 2,000 licensees. At the inflation-adjusted $27.47 per hour, the agency estimates that maintaining and retrieving the labels will cost the industry an additional $13,735 annually. Total industry costs would amount to only about $14 per mill.

For the proposed rule, the agency had estimated a large savings in the paperwork burden due to the elimination of the MFA requirements. Over the past 5 years, the agency has received approximately 3,300 MFA's

per year including both original applications and MFA supplements. In the past, FDA surveyed several feed mills and animal drug manufacturers, and determined that it took industry about 2 hours to complete an MFA application. Therefore, FDA estimated that the rule would save industry over $158,000 per year, or approximately $79 per mill per year, on average. FDA has adjusted this saving for wage inflation to approximately $181,000 per year, or about $91 per mill each year. The mills that have routinely submitted a larger number of MFA's would realize a larger savings than those mills that routinely submit few MFA's. The agency did not receive comments on this estimate and retains the inflation-adjusted amount for the final rule.

FDA also predicted that it would experience an administrative cost saving in response to the medicated feed mill licensing requirement. Since 1994, the agency has spent approximately $180,000 per year for a contractor to process the MFA's. In contrast, it would take FDA only about 40 minutes to process each medicated feed mill license application, at a cost of $25 per hour for a GS–13 government employee. The first year, the agency estimated that it would cost $33,500 to process the expected 2,000 applications, and $10,000 for starting up a tracking and indexing computerized data base. Further, it would cost only about $1,700 to process the 100 applications for each year thereafter.

Adjusting for wage inflation for the final rule, the agency expects the first year cost to process the applications to be about $37,200, and $11,500 for the tracking and indexing computerized data base. Application processing for subsequent years is expected to cost about $1,850 per year. The agency did not receive comments on these estimates of government cost savings and retains the inflation-adjusted amounts for the final rule.

The Small Business Administration (SBA) defines all manufacturers of prepared feeds and feed ingredients for animals and fowls having 500 employees or less as a small business. The agency previously estimated that approximately 20 percent of the affected feed mills belong to large conglomerates that have an overall employee count higher than 500. Therefore, the remaining 80 percent of the affected facilities would be considered small feed mills by SBA's standards. However, as described previously, the agency has determined that the rule will provide a net economic savings for all facilities. Therefore, in accordance with the Regulatory Flexibility Act, FDA certifies that this rule will not have a significant effect on a substantial number of small entities.

VII. Federalism

FDA has analyzed the final rule in accordance with the principles and criteria set forth in Executive Order 13132 and has determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given as follows. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing each collection of information.

Title: Medicated Feed Mill License Application.

Description: This final rule implements the ADAA's medicated feed mill licensing provisions. It requires that any medicated feed manufacturing facility seeking a license submit an application to FDA. In § 515.10 of the final regulations, FDA proposed that medicated feed mill license applications be submitted on FDA Form 3448, ''Medicated Feed Mill License Application.''

Section 515.11 of the final regulation specifies that supplemental applications must be submitted for a change in ownership and/or change in mailing address, which also would be submitted on FDA Form 3448. Furthermore, § 515.23 of the regulations provides for voluntary revocation of a license. A medicated feed licensee would submit, in writing to FDA, a request for voluntary revocation of a license.

Finally, § 515.30 of the regulation provides procedures refusing to approve license applications when, among other reasons, the application is incomplete, false or misleading or the manufacturing, processing, and packaging of the animal feed do not comply with applicable provisions of the act. A medicated feed manufacturing facility would have the option to submit a request in writing for a hearing in response to the agency's proposal to refuse to approve a medicated feed mill application.

Description of Respondents: Medicated Feed Manufacturing Facilities.

In the **Federal Register** of July 30, 1997 (62 FR 40765), interested persons were requested to send comments regarding this collection of information to OMB by August 29, 1997. In response to this notice OMB received one comment regarding the paperwork aspect of this collection of information. The comment argued that the agency's estimate of the burden of the proposed collection of information was inaccurate in the following two instances: (1) In assuming that the only costs that will be incurred are the paperwork costs associated with applying for a facility license, and (2) in the estimate of $10,000 for tracking and indexing a computerized data base.

Regarding instance (1), the comment stated that the agency's assumption is inaccurate in that no consideration has been given to the capital and operating costs for the retrieval and maintenance of approved labeling for medicated feeds. The comment stated that this burden applies to sponsors under section 512(a)(1)(B) of the act and to licensed feed mills under proposed § 510.305.

CVM has evaluated this part of the comment and agrees that the agency did not address the cost for the licensed feed mill to maintain and retrieve approved Blue Bird labels as required under § 510.305. Table 3 of this document provides an estimate of that cost at a total of 500 hours annually for an estimated 2,000 licensees. This covers the cost of obtaining the label from either the drug sponsor or FDA and keeping it in a file. CVM estimates that most licensed feed establishments would only have 1 to 10 Blue Bird labels to maintain and retrieve. A few, primarily the multiple facilities, may have many more, but would only maintain and retrieve these labels at their home office. Thus the average estimate of 15 minutes per licensee takes these factors into account.

The agency has concluded that it did not err in excluding this burden for drug sponsors because the provision the comment cited, which requires retrieval and maintenance of approved labeling, applies only to feed mills, not to sponsors. The burden is on feed mills to retrieve the approved labeling either from the sponsor or FDA.

Regarding instance (2), the comment maintained that unless access to this data base is made available to sponsors and consignees, it would be logical to assume that similar expenses would be incurred by each sponsor and consignee maintaining a parallel data base in order to ensure their compliance with section 512(a)(1)(B) of the act. The comment argued that the most effective approach to eliminate this unnecessary burden would be for CVM to provide public

access to its data base through the CVM home page. FDA has evaluated this comment, and CVM has put a list of approved licensees on the Internet, and public access has been granted.

FDA had estimated that 2,000 respondents would apply for feed mill licenses under § 515.10 during the first year and that a total of 500 hours would be required for them to respond. During the first 18 months (by the transition provisions, respondents had 18 months to obtain a license), only 1,250 respondents applied for licenses. FDA estimated that during each succeeding year, 100 new respondents would request feed mill licenses. Based on current information, that number appears to be a reasonable estimate of the number of respondents. The agency has received approximately 70 requests for licenses in the year following the first 18 months. FDA also estimated that there would be 25 respondents for supplemental applications (§ 515.11), 50 for voluntary revocations (§ 515.23), and 0.15 for notices of opportunity for hearing (§ 515.30). Those numbers also appear to have been reasonable estimates.

This final rule contains the original provisions of part 515, as proposed, and amends these provisions only for further clarity. As a result of the comment(s) received, an estimate of an annual recordkeeping burden (Table 3) has been added to the burden chart, under § 510.305. Thus, the original annual reporting burden estimate has been changed to include annual recordkeeping requirements.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN: FIRST YEAR[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10	2,000	1	2,000	0.25	500
515.11	25	1	25	0.25	6.25
515.23	50	1	50	0.25	12.25
515.30	0.15	1	0.15	24	3.6
Total					522.1

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN: EACH SUCCEEDING YEAR[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10	100	1	100	0.25	25
515.11	25	1	25	0.25	6.25
515.23	50	1	50	0.25	12.25
515.30	0.15	1	0.15	24	3.6
Total					47.1

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305	2,000	1	2,000	0.25	500

[1] There are no capital cost or operating and maintenance cost associated with this collection of information.

Individuals or organizations may submit comments on this burden estimate or any other aspect of these collection of information provisions, including suggestions for reducing the burden, and direct them to William Price (address above).

The information collection provisions in this final rule have been approved under OMB control number 0910–0356. This approval expires October 31, 2000. An agency may not conduct or sponsor, and a person is not required to provide, a collection of information unless the collection of information displays a currently valid OMB control number.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA Medicated Feed Task Force, ''Medicated Feed Task Force Report,'' December 1978.

2. Employment and Earnings, U.S. Department of Labor Bureau and Labor Statistics, vol. 43, No. 1, p. 205, January 1996.

3. U.S. Department of Labor Bureau of Labor Statistics; ''ftp://ftp.bls.gov/pub/special.requests/lf/aat39.txt''.

List of Subjects

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 225

Animal drugs, Animal feeds, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 514 and 515

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter I is amended to read as follows:

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. The authority citation for 21 CFR part 207 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 355, 360, 360b, 371, 374; 42 U.S.C. 262.

2. Section 207.10 is amended by revising paragraph (f) to read as follows:

§ 207.10 Exemptions for domestic establishments.

* * * * *

(f) Persons who only manufacture the following:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds, and/or;

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(3) Persons who manufacture free-choice feeds, as defined in § 510.455 of this chapter, or medicated liquid feeds, as defined in § 558.5 of this chapter, where a medicated feed mill license is required are not exempt.

* * * * *

§ 207.20 [Amended]

3. Section 207.20 *Who must register and submit a drug list* is amended in paragraph (c) by removing the words ''medicated feed application,'' and adding in its place ''medicated feed mill license application,''.

§ 207.21 [Amended]

4. Section 207.21 *Times for registration and drug listing* is amended in paragraph (a) in the second sentence, by removing the words ''medicated feed application,'' and adding in its place ''medicated feed mill license application,''.

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

5. The authority citation for 21 CFR part 225 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 374.

6. Section 225.1 is amended by revising paragraph (b)(2) and by adding paragraph (c) to read as follows:

§ 225.1 Current good manufacturing practice.

* * * * *

(b)(1) * * *

(2) The regulations in §§ 225.10 through 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed mill license is required. The regulations in §§ 225.120 through 225.202 apply to facilities manufacturing solely medicated feeds for which an approved license is not required.

(c) In addition to the recordkeeping requirements in this part, Type B and Type C medicated feeds made from Type A articles or Type B feeds under approved NADA's and a medicated feed mill license are subject to the requirements of § 510.301 of this chapter.

7. Section 225.58 is amended in paragraph (b)(1) by revising the first sentence to read as follows:

§ 225.58 Laboratory controls.

* * * * *

(b) * * *

(1) For feeds requiring a medicated feed mill licence (Form FDA 3448) for their manufacture and marketing, at least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by approved official methods, at periodic intervals during the calendar year, unless otherwise specified in this chapter. * * *

* * * * *

8. Section 225.115 *Complaint files* is amended by revising paragraph (b)(2) to read as follows:

§ 225.115 Complaint files.

* * * * *

(b) * * *

(2) For medicated feeds whose manufacture require a medicated feed mill license (Form FDA 3448), records and reports of clinical and other experience with the drug shall be maintained and reported, under § 510.301 of this chapter.

PART 510—NEW ANIMAL DRUGS

9. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

10. Section 510.7 is amended by revising paragraphs (a)(1) and (a)(2) to read as follows:

§ 510.7 Consignees of new animal drugs for use in the manufacture of animal feed.

(a) * * *

(1) Holds a license issued under § 515.20 of this chapter; or

(2) Will, if the consignee is not the user of the drug, ship such drug only to a holder of an approved application under § 515.10 of this chapter.

* * * * *

11. Section 510.301 is amended to revise the section heading to read as follows:

§ 510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved medicated feed mill license application is in effect.

* * * * *

12. Section 510.305 is revised to read as follows:

§ 510.305 Maintenance of copies of approved medicated feed mill licenses to manufacture animal feed bearing or containing new animal drugs.

Each applicant shall maintain in a single accessible location:

(a) A copy of the approved medicated feed mill license (Form FDA 3448) on the premises of the manufacturing establishment; and

(b) Approved labeling for each Type B and/or Type C feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

PART 514—NEW ANIMAL DRUG APPLICATIONS

13. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

§ 514.2 [Removed]

14. Section 514.2 *Applications for animal feeds bearing or containing new animal drugs* is removed.

§ 514.9 [Removed]

15. Section 514.9 *Supplemental applications for animal feeds bearing or containing new animal drugs* is removed.

§ 514.105 [Amended]

16. Section 514.105 *Approval of applications* is amended by removing the introductory text of paragraph (a) and by removing paragraph (b), and by redesignating paragraphs (a)(1) and (a)(2) as paragraphs (a) and (b), and by amending newly redesignated paragraph

(a) by removing the first word ''He'' and adding in its place ''The Commissioner ''.

§ 514.111 [Amended]

17. Section 514.111 *Refusal to approve an application* is amended by removing paragraph (b) and by redesignating paragraph (c) as paragraph (b).

§ 514.112 [Removed]

18. Section 514.112 *Return of applications for animal feeds bearing or containing new animal drugs* is removed.

§ 514.115 [Amended]

19. Section 514.115 *Withdrawal of approval of applications* is amended in paragraphs (a), (b), (c), and (d) by removing the phrase ''or (m)(2)''; in paragraph (c)(1) by removing the phrases ''or (m)(5)(A)'' and ''or (m)(5)(B)''; in paragraph (c)(3) by removing the phrase ''or animal feed', and in paragraph (e) by removing the second sentence.

20. Section 514.201 is revised to read as follows:

§ 514.201 Procedures for hearings.

Hearings relating to new animal drugs under section 512(d) and (e) of the act shall be governed by part 12 of this chapter.

21. Part 515 is added to read as follows:

PART 515—MEDICATED FEED MILL LICENSE

Subpart A—Applications

Sec.
515.10 Medicated feed mill license applications.
515.11 Supplemental medicated feed mill license applications.

Subpart B—Administrative Actions on Licenses

515.20 Approval of medicated feed mill license applications.
515.21 Refusal to approve a medicated feed mill license application.
515.22 Suspension and/or revocation of approval of a medicated feed mill license.
515.23 Voluntary revocation of medicated feed mill license.
515.24 Notice of revocation of a medicated feed mill license.
515.25 Revocation of order refusing to approve a medicated feed mill license application or suspending or revoking a license.
515.26 Services of notices and orders.

Subpart C—Hearing Procedures

515.30 Contents of notice of opportunity for a hearing.
515.31 Procedures for hearings.

Subpart D—Judicial Review

515.40 Judicial review.

Authority: 21 U.S.C. 360b, 371.

Subpart A—Applications

§ 515.10 Medicated feed mill license applications.

(a) Medicated feed mill license applications (Forms FDA 3448) may be obtained from the Public Health Service, Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785, or electronically from the Center for Veterinary Medicine home page at ''http://www.fda.gov/cvm''.

(b) A completed medicated feed mill license must contain the following information:

(1) The full business name and address of the facility at which the manufacturing is to take place.

(2) The facility's FDA registration number as required by section 510 of the Federal Food, Drug, and Cosmetic Act (the act).

(3) The name, title, and signature of the responsible individual or individuals for that facility.

(4) A certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled in accordance with the applicable regulations published under section 512(i) of the act.

(5) A certification that the methods used in, and the facilities and controls used for, manufacturing, processing, packaging, and holding such animal feeds conform to current good manufacturing practice as described in section 501(a)(2)(B) of the act and in part 225 of this chapter.

(6) A certification that the facility will establish and maintain all records required by regulation or order issued under sections 512(m)(5)(A) or 504(a)(3)(A) of the act, and will permit access to, or copying or verification of such records.

(7) A commitment that current approved Type B and/or Type C medicated feed labeling for each Type B and/or Type C medicated feed to be manufactured will be in the possession of the feed manufacturing facility prior to receiving the Type A medicated article containing such drug.

(8) A commitment to renew registration every year with FDA as required in §§ 207.20 and 207.21 of this chapter.

(c) Applications must be completed, signed, and submitted to the Division of Animal Feeds (HFV–220), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

(d) Applications that are facially deficient will be returned to the applicant. All reasons for the return of the application will be made known to the applicant.

(e) Upon approval, the original copy of the application will be signed by an authorized employee of FDA designated by the Commissioner of Food and Drugs, and a copy will be returned to the applicant.

§ 515.11 Supplemental medicated feed mill license applications.

(a) After approval of a medicated feed mill license application to manufacture animal feed, a supplemental application shall be submitted for a change in ownership and/or a change in mailing address of the facility site.

(b) Each supplemental application should be accompanied by a fully completed Form FDA 3448 and include an explanation of the change.

(c) Within 30 working days after a supplemental application has been filed, if the Commissioner of Food and Drugs determines that the application provides adequate information respecting the change in ownership and/or postal address of the facility site, then an authorized employee of the Food and Drug Administration designated by the Commissioner shall notify the applicant that it is approved by signing and mailing to the applicant a copy of the Form FDA 3448. Supplemental applications that do not provide adequate information shall be returned to the applicant and all reasons for the return of the application shall be made known to the applicant.

Subpart B—Administrative Actions on Licenses

§ 515.20 Approval of medicated feed mill license applications.

Within 90 days after an application has been filed under § 515.10, if the Commissioner of Food and Drugs (the Commissioner) determines that none of the grounds for denying approval specified in section 512(m)(3) of the Federal Food, Drug, and Cosmetic Act (the act) applies, an authorized employee of the Food and Drug Administration designated by the Commissioner shall notify the applicant that it is approved by signing and mailing to the applicant a copy of the Form FDA 3448.

§ 515.21 Refusal to approve a medicated feed mill license application.

(a) The Commissioner of Food and Drugs (the Commissioner) shall within 90 days, or such additional period as may be agreed upon by the Commissioner and the applicant, after

the filing of an application under § 515.10, inform the applicant in writing of his/her intention to issue a notice of opportunity for a hearing on a proposal to refuse to approve the application, if the Commissioner determines upon the basis of the application, on the basis of a preapproval inspection, or upon the basis of any other information before him that:

(1) The application is incomplete, false, or misleading in any particular; or

(2) The methods used in and the facilities and controls used for the manufacturing, processing, and packaging of such animal feed are not adequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

(3) The facility manufactures animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture or labels animal feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are published under section 512(i) of the act.

(b) The Commissioner, as provided in § 515.30, shall expeditiously notify the applicant of an opportunity for a hearing on the question of whether such application is approvable, unless by the 30th day following the date of issuance of the letter informing the applicant of the intention to issue a notice of opportunity for a hearing the applicant:

(1) Withdraws the application; or

(2) Waives the opportunity for a hearing; or

(3) Agrees with the Commissioner on an additional period to precede issuance of such notice of hearing.

§ 515.22 Suspension and/or revocation of approval of a medicated feed mill license.

(a) The Secretary of Health and Human Services may suspend a medicated feed mill license approved under section 512(m)(2) of the Federal Food, Drug, and Cosmetic Act (the act) and give the person holding the medicated feed mill license application prompt notice of this action and afford the applicant the opportunity for an expedited hearing on a finding that there is an imminent hazard to the health of man or of the animals for which such animal feed is intended.

(b) The Commissioner of Food and Drugs (the Commissioner) shall notify in writing the person holding an application approved under section 512(m)(2) of the act and afford an opportunity for a hearing on a proposal to revoke approval of such application if the Commissioner finds:

(1) That the application contains any untrue statement of a material fact; or

(2) That the applicant has made any changes that would cause the application to contain any untrue statements of material fact or that would affect the safety or effectiveness of the animal feeds manufactured at the facility unless the applicant has supplemented the application by filing a supplemental application under § 515.11.

(c) The Commissioner may notify in writing the person holding an application approved under section 512(m)(2) of the act and afford an opportunity for a hearing on a proposal to revoke approval of such application if the Commissioner finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under sections 512(m)(5)(A) or 504(a)(3)(A) of the act, or the applicant has refused to permit access to, or copying, or verification of, such records as required by sections 512(m)(5)(B) or 504(a)(3)(B) of the act; or

(2) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(3) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(4) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the facility has manufactured, processed, packed, or held animal feed bearing or containing a new animal drug adulterated under section 501(a)(6) of the act, and the facility did not discontinue the manufacture, processing, packing, or holding of such animal feed within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of.

§ 515.23 Voluntary revocation of medicated feed mill license.

A license issued under section 512(m)(2) of the Federal Food, Drug, and Cosmetic Act (the act) will be revoked on the basis of a request for its revocation submitted in writing by a responsible individual holding such license on the grounds that the facility no longer manufactures any animal feed covered under § 558.4(b) of this chapter. A written request for such revocation shall be construed as a waiver of the opportunity for a hearing as otherwise provided for in this section. Revocation of approval of a medicated feed mill license under the provisions of this paragraph shall be without prejudice.

§ 515.24 Notice of revocation of a medicated feed mill license.

When a license approved under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) is revoked by the Commissioner of Food and Drugs (the Commissioner), the Commissioner will give appropriate public notice of such action by publication in the **Federal Register**.

§ 515.25 Revocation of order refusing to approve a medicated feed mill license application or suspending or revoking a license.

The Commissioner of Food and Drugs (the Commissioner), upon his/her own initiative or upon request of an applicant stating reasonable grounds therefor and if the Commissioner finds that the facts so require, may issue an order approving a medicated feed mill license application that previously has had its approval refused, suspended, or revoked.

§ 515.26 Services of notices and orders.

All notices and orders under this part 515 and section 512 of the Federal Food, Drug, and Cosmetic Act (the act) pertaining to medicated feed mill licenses shall be served:

(a) In person by any officer or employee of the Department of Health and Human Services designated by the Commissioner of Food and Drugs; or

(b) By mailing the order by certified mail addressed to the applicant or respondent at the applicant or respondent's last known address in the records of the Food and Drug Administration.

Subpart C—Hearing Procedures

§ 515.30 Contents of notice of opportunity for a hearing.

(a) The notice to the applicant of opportunity for a hearing on a proposal by the Commissioner of Food and Drugs (the Commissioner) to refuse to approve a medicated feed mill license application or to revoke the approval of a medicated feed mill license will specify the grounds upon which the Commissioner proposes to issue this order. On request of the applicant, the Commissioner will explain the reasons for the action. The notice of opportunity for a hearing will be published in the **Federal Register** and will specify that the applicant has 30 days after issuance of the notice within which the Commissioner is required to file a written appearance electing whether:

(1) To avail himself of the opportunity for a hearing; or

(2) Not to avail himself of the opportunity for a hearing.

(b) If the applicant fails to file a written appearance in answer to the notice of opportunity for hearing, this failure will be construed as an election not to avail himself of the opportunity for the hearing, and the Commissioner without further notice may enter a final order.

(c) If the applicant elects to avail himself of the opportunity for a hearing, the applicant is required to file a written appearance requesting the hearing within 30 days after the publication of the notice, giving the reason why the application should not be refused or the medicated feed mill license should not be revoked, together with a well-organized and full-factual analysis of the information the applicant is prepared to prove in support of his opposition to the Commissioner's proposal. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing there is a genuine and substantial issue of fact that requires a hearing. When it clearly appears from the information in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the refusal to approve the application or the revocation of approval of the application, the Commissioner will enter an order on this information, stating his/her findings and conclusions. If a hearing is requested and is justified by the applicant's response to the notice of opportunity for a hearing, the issues will be defined, an Administrative Law Judge will be named, and the Judge shall issue a written notice of the time and place at which the hearing will commence. In the case of denial of approval, such time shall be not more than 90 days after the expiration of such 30 days unless the Administrative Law Judge and the applicant otherwise agree; and, in the case of withdrawal of approval, such time shall be as soon as practicable.

(d) The hearing will be open to the public; however, if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies in the appearance.

§ 515.31 Procedures for hearings.

Hearings relating to new animal drugs under section 512(m)(3) and (m)(4) of the Federal Food, Drug, and Cosmetic Act (the act) shall be governed by part 12 of this chapter.

Subpart D—Judicial Review

§ 515.40 Judicial review.

The transcript and record shall be certified by the Commissioner of Food and Drugs (the Commissioner). In any case in which the Commissioner enters an order without a hearing under § 314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

22. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: U.S.C. 360b, 371.

§ 558.3 [Amended]

23. Section 558.3 *Definitions and general considerations applicable to this part* is amended in paragraphs (b)(3) and (b)(4) by removing the phrase ''an application approved under § 514.105(b) of this chapter'' and adding in its place ''a medicated feed mill license application approved under § 515.20 of this chapter''; and in paragraphs (b)(2) and (b)(5) by removing ''§ 514.105(a)'' and adding in its place ''§ 514.105''.

24. Section 558.4 is amended by revising the section heading and paragraphs (a), (b), and (c) to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds; and

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(c) The use of Type B and Type C medicated feeds shall also conform to the conditions of use provided for in subpart B of this part and in §§ 510.515 and 558.15 of this chapter.

* * * * *

Dated: August 12, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–29856 Filed 11–18–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CO–001–0035a; UT–001–0023a; WY–001–0004a; FRL–6471–4]

Approval and Promulgation of Air Quality Implementation Plans; States of Colorado, Utah and Wyoming; General Conformity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving General Conformity SIP revisions submitted by the Governor of Wyoming on March 14, 1995; submitted by the Governor of Utah on February 12, 1996; and submitted by the Governor of Colorado on September 16, 1997. These SIP revisions were submitted to meet a requirement of section 176(c) of the Clean Air Act.

DATES: This direct final rule is effective on January 18, 2000, without further notice, unless EPA receives adverse comments by December 20, 1999. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments may be mailed to: Richard R. Long, Director, Air and Radiation Program, Mailcode 8P–AR, United States Environmental Protection Agency, Region VIII, 999

18th Street, Suite 500, Denver, Colorado 80202–2466.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the following offices:

United States Environmental Protection Agency, Region VIII, Air and Radiation Program, 999 18th Street, Suite 500, Denver, Colorado 80202–2466; and,

United States Environmental Protection Agency, Air and Radiation Docket and Information Center, 401 M Street, SW, Washington, DC 20460.

Copies of the State documents relevant to this action are available for public inspection at:

Colorado Air Pollution Control Division, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, Colorado, 80246–1530.

Utah Division of Air Quality, Department of Environmental Quality, 150 North 1950 West, Salt Lake City, Utah, 84114–4820.

Air Quality Division, Department of Environmental Quality, 122 West 25th Street, Cheyenne, Wyoming, 82002.

FOR FURTHER INFORMATION CONTACT: Jeff Houk, Air and Radiation Program, Mailcode 8P–AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202–2466; Telephone number: (303) 312–6446.

SUPPLEMENTARY INFORMATION: Throughout this document, wherever ''we,'' ''our,'' or ''us'' is used, we mean EPA.

I. Summary of EPA's Actions

Today we are approving the General Conformity SIP revisions submitted by the Governor of Wyoming on March 14, 1995; submitted by the Governor of Utah on February 12, 1996; and submitted by the Governor of Colorado on September 16, 1997. Our approval means that the SIP criteria and procedures will govern future general conformity determinations instead of the Federal rules at 40 CFR part 93, subpart B.

II. Evaluation of the States' Submittals

Section 110(k) of the Act addresses our actions on submissions of SIP revisions. The Act also requires States to observe certain procedures in developing SIP revisions. Section 110(a)(2) of the Act requires that each SIP revision be adopted after reasonable notice and public hearing. We have evaluated the States' submissions and determined that the necessary procedures were followed. We found that Wyoming's SIP revision was administratively and technically complete in a letter to the Governor dated May 26, 1995. Utah's SIP revision became complete by operation of law on April 12, 1996. Colorado's SIP revision became complete by operation of law on November 15, 1997.

The States' General Conformity SIP revisions must contain criteria and procedures that are at least as stringent as those in the Federal rule. States may incorporate the Federal rule into State rules.

Wyoming's New Air Quality Standards Regulation Section 32

We are approving Wyoming's General Conformity SIP revision because section 32 includes every requirement of the federal rule except for 40 CFR 93.151 (''State Implementation Plan (SIP) revision''), which discusses how the Federal and State conformity rules interact. State rules govern conformity determinations once we approve them. 40 CFR 93.151 has the same effect whether or not it is incorporated into the State SIP because it specifies that any part of the Federal rule not included in EPA-approved State rules remains in effect at the federal level.

Wyoming also added a definition to its rule that wasn't included in the Federal rule, for ''CAA'' (Clean Air Act), and slightly modified the definitions for ''Milestone,'' and ''Nonattainment Area (NAA).'' We agree with these minor changes to the Federal rule language.

Utah's General Conformity SIP Revision

We are approving Utah's General Conformity SIP, which simply adopts the Federal rule into State rules. It was adopted in three separate actions: (1) A new section XXII to the SIP, General Conformity; (2) a new State rule, R307–2–30, incorporating this section of the SIP into State rules, and (3) a new rule R307–19, formally incorporating the Federal rule into State rules.

The effective date for the Federal rule cited in the State rule and the SIP (November 30, 1992) is incorrect. The Federal rule took effect on January 31, 1994. This error does not affect the applicability or the approvability of Utah's SIP.

Colorado's revisions to its Regulation No. 10, ''Criteria for Analysis of Conformity''

We are approving these revisions, which incorporate 40 CFR part 51, subpart W, and 40 CFR 6.303 into the State rule. Colorado should have incorporated the Federal conformity rule (40 CFR part 93, subpart B) rather than the General Conformity SIP requirements of 40 CFR part 51, subpart W. However, these two regulations are identical except for the conformity SIP requirement itself (40 CFR 51.851(a)), which no longer applies because the State has submitted its SIP.

Colorado also incorporated changes that we made to 40 CFR part 6 at the time we finalized our conformity rule. 40 CFR part 6 contains regulations to ensure that our actions meet the requirements of the National Environmental Policy Act of 1969 and the Council on Environmental Quality's implementing regulations of November 29, 1978 (43 FR 55978). We revised 40 CFR 6.303 to reference the general conformity requirements and to state that our actions must meet these requirements. We don't require states to incorporate these requirements into general conformity SIPs, but they can.

III. Background on our General Conformity Requirements

The SIPs we are approving today were submitted to meet a requirement of Clean Air Act section 176(c), which spells out the Act's conformity requirements and directs each State to submit conformity SIPs. Under section 176(c), ''no Federal department, agency, or instrumentality shall engage in, support in any way or provide financial assistance for, license or permit or approve any activity which does not conform to a SIP that has been approved or promulgated pursuant to the Act.'' This section defines conformity as compliance with the SIP's purpose of attaining the National Ambient Air Quality Standards, and states that federal activities will not cause or contribute to a new violation of any standard in any area, increase the frequency or severity of an existing violation of any standard in any area, or delay timely attainment of a standard or any required interim emission reductions or other milestones in any area.

Section 176(c)(4)(A) requires us to issue criteria and procedures for determining conformity of all Federal actions to applicable SIPs. 40 CFR part 93, subpart A spells out criteria and procedures for determining conformity of Federal actions related to transportation projects funded or approved under Title 23 U.S.C. or the Federal Transit Act. 40 CFR part 93, Subpart B (''Determining Conformity of General Federal Actions to State or Federal Implementation Plans'') spells out criteria and procedures for determining conformity of all other Federal actions. These are the requirements that we are acting on with

respect to the State SIPs in this approval.

IV. Final Action

In this action, EPA is approving the General Conformity SIP revisions submitted by the Governor of Wyoming on March 14, 1995; submitted by the Governor of Utah on February 12, 1996; and submitted by the Governor of Colorado on August 19, 1998.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective January 18, 2000, without further notice unless the Agency receives adverse comments by December 20, 1999.

If EPA receives such comments, then we will publish a timely withdrawal of the direct final rule informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this rule. Any parties interested in commenting on this rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on January 18, 2000, and no further action will be taken on the proposed rule.

Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Orders 12875

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation.

In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132, (64 FR 43255 (August 10, 1999),) which will take effect on November 2, 1999. In the interim, the current Executive Order 12612, (52 FR 41685 (October 30, 1987),) on federalism still applies. This rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612. The rule affects only three states, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation.

In addition, E.O. 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.*, v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed

into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a ''major'' rule as defined by 5 U.S.C. 804(2).

H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 18, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: October 13, 1999

Jack W. McGraw,

Acting Regional Administrator, Region VIII.

Chapter I, title 40, parts 52 and 81 of the Code of Federal Regulations are amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart G—Colorado

2. Section 52.320 is amended by adding paragraph (c)(85) to read as follows:

§ 52.320 Identification of plan.

* * * * *

(c) * * *

(85) On September 16, 1997, the Governor of Colorado submitted revisions to Regulation No. 10 ''Criteria for Analysis of Conformity'' that incorporate the General Conformity requirements of 40 CFR part 51, Subpart W into State regulation.

(i) Incorporation by reference.

(A) Regulation No. 10 ''Criteria for Analysis of Conformity'', 5 CCR 1001–12, as adopted on October 17, 1996, effective December 30, 1996.

Subpart TT—Utah

3. Section 52.2320 is amended by adding paragraph (c)(42) to read as follows:

§ 52.2320 Identification of plan.

* * * * *

(c) * * *

(42) On February 12, 1996, the Governor of Utah submitted revisions submitted revisions to the SIP that incorporate the General Conformity requirements of 40 CFR part 93, subpart B into the SIP and State regulation.

(i) Incorporation by reference.

(A) UACR R307–2–30, Section XXII, General Conformity, as adopted on October 4, 1995, effective October 12, 1995.

(B) UACR R307–19, General Conformity, as adopted on October 4, 1995, effective October 12, 1995.

Subpart ZZ—Wyoming

4. Section 52.2620 is amended by adding paragraph (c)(28) to read as follows:

§ 52.2620 Identification of plan.

* * * * *

(c) * * *

(28) On March 14, 1995, the Governor of Wyoming submitted revisions to the SIP that incorporate the General Conformity requirements of 40 CFR part 93, Subpart B into State regulation.

(i) Incorporation by reference.

(A) Section 32 of the Wyoming Air Quality Standards, ''Conformity of General Federal Actions to State Implementation Plans,'' effective February 13, 1995.

[FR Doc. 99–30232 Filed 11–18–99; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 63, 261, and 266

[FRL–6477–9]

RIN 2050–AE01

NESHAPS: Final Standards for Hazardous Air Pollutants for Hazardous Waste Combustors

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: On June 19, 1998, EPA published the Revised Standards for Hazardous Waste Combustors Final Rule and on September 30, 1999 published the Hazardous Waste Combustors NESHAP Final Rule. In today's action we are clarifying our intention associated with the Notification of Intent to Comply and Progress Report requirements of the 1998 rule. Additionally, we are correcting a typographical error in the

comparable fuels specification table and an omission pertaining to residue testing requirements in the 1999 final rule.

EFFECTIVE DATE: This rule is effective on November 19, 1999.

ADDRESSES: The public may obtain a copy of this technical correction at the RCRA Information Center (RIC), located at Crystal Gateway One, 1235 Jefferson Davis Highway, First Floor, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at (800) 424–9346 (toll free) or (703) 920–9810 in the Washington, DC metropolitan area. For information on this rule pertaining to the notification requirements, contact David Hockey (5302W), Office of Solid Waste, 401 M Street, SW, Washington, DC 20460, (703) 308–8846, e-mail address is ''hockey.david@epa.gov.'' For information pertaining to the residue requirements, contact Larry Gonzalez (5302W), Office of Solid Waste, 401 M Street, SW, Washington, DC 20460, (703) 308–8468, e-mail address is ''gonzalez.larry@epa.gov.''

SUPPLEMENTARY INFORMATION

I. Reasons and Basis for Today's Action

The June 1998 Revised Standards for Hazardous Waste Combustors rule (June 19, 1998, 63 FR 33782) includes a requirement that sources submit progress reports to support declarations made in the source's Notification of Intent to Comply (63 FR at 33820). We are amending two of these requirement in today's action to make our original intent more clear. The third amendment is to the September 1999 rule and it involves a typographical error in the comparable fuels specification table revised at 64 FR 53076 which we are correcting today.

The fourth amendment we are correcting is an inadvertent omission pertaining to residue testing requirements for devices burning hazardous waste fuels while processing Bevill amendment raw materials. In the final rule setting standards for hazardous waste combustors (Sept. 30, 1999, 64 FR at 53076), we modified a number of provisions found in 40 CFR parts 264, 265, and 266. In the revisions to 40 CFR 266.112, we inadvertently omitted a note to the Appendix VIII table to Part 266 that limits the requirement for testing to only those compounds that have a nonwastewater concentration limit under the F039 waste code for leachates found at 40 CFR 268.40.

II. Corrections to the June 19, 1998 Final Rule

A. Notification of Intent To Comply

Today's changes to 40 CFR 63.1210 clarify that only those elements enumerated in § 63.1210(b)(1)(ii) which actually apply to the particular source must be addressed by the source in its notice of intent to comply. It was not EPA's intent to require sources to spend time submitting information, or addressing issues, of no applicability to their actual situation. Since some of the elements that are required to be submitted may not be necessary for every source in coming into compliance, this technical amendment clarifies that the elements of paragraph (b)(1)(ii) are only applicable to a source if necessary to bring that source into compliance. A source itself makes this determination based upon its own particular situation.

B. Progress Reports

The changes to § 63.1211 of the progress report requirements clarify our original intent with respect to the documentation of progress towards compliance. In paragraph (b)(1), we require sources to demonstrate their progress via three elements: (i) Development of engineering designs for physical modifications; (ii) submittal of applicable construction applications; and (iii) a commitment of resources. As currently expressed, element (iii) requires the source to enter into ''binding contractual commitments'' to purchase, build and install needed equipment. Section 63.1211(b)(1) (as promulgated at 63 FR 33820 (June 19, 1998)). Sources have since voiced concern with the ''contractual'' element because it can be read to imply that upgrading requires arrangements to be made with entities other than the source itself. This was not EPA's intent, nor would such a restriction make environmental sense since there is no inherent problem with a source performing its own upgrading if it is able to do so. Some sources thus will not have to enter into contracts with other entities, but will be able to use in-house personnel or existing agreements to purchase, fabricate, and install any equipment needed to comply with the emission standards. Therefore, we are better describing our intent by amending the language of the ''contractual'' element to more broadly include these other situations. This change merely restates the language of element (iii) while continuing to meet our original intent for the demonstration of progress, as discussed in the preamble language in the June 19, 1999 **Federal Register** (63 FR at 33810). This section also makes the necessary conforming changes to the rest of paragraph (b).

III. Corrections to the September 30, 1999 Final Rule

A. Comparable Fuels Specification Table

In the September 30, 1999 (64 FR 53076) final rule, we corrected several of the exemption specifications contained in Table 1 to section 261.38—Detection and Detection Limit Values for Comparable Fuel Specification. A typographical error occurred during printing which misprinted the Antimony specification by incorrectly inserting the standard for Arsenic which appears below Antimony in the table. The correct value for the Antimony specification should be a concentration limit of 12 mg/kg at 10,000 BTU/lb. Today's rule corrects this typographical error.

B. Regulation of Residues

In the September 30, 1999 (64 FR 53076) final rule, the Agency revised the requirements governing the classification of residues from certain industrial furnaces that burn hazardous waste-derived fuels. Specifically, the existing provisions at § 266.112 create an objective test to determine whether residues from these devices have been ''significantly affected'' by their hazardous waste combustion activities. Residues that have been ''significantly affected'' are no longer eligible for Bevill exempt status, and so are subject to subtitle C regulation. The ''significantly affected'' determination requires certain types of testing to determine hazardous constituent concentration levels in the wastes generated by the industrial furnace. We amended part of that testing requirement in the September 30, 1999 final rule, and are correcting those amendments in this notice.

The 1999 revisions require hazardous waste combustion sources regulated under the BIF Rule (40 CFR 266, Subpart H) to test their residues for all of the compounds specified in the Appendix VIII table to Part 266, and to verify that their residues do not exceed the F039 nonwastewater concentration limits to retain their Bevill exempt status (64 FR at 53076). We also revised the list of compounds to be tested by including specific dioxin compounds on the table (64 FR 53076). However, in revising the residue testing requirements, we inadvertently failed to include a provision that allows sources not to analyze for those compounds on the table that lack F039 nonwastewater concentration limits. This omission is

contrary to preamble language of the 1999 final rule. For example at 64 FR 52995, we state that the revised § 266.112 (b)(2) measurement requirements apply only to discreet homologues of dioxin compounds (tetra, penta, and hexa-homologues) because these homologues are the only ones with established F039 concentration limits. Following promulgation of the September 1999 final rule, we determined that nine additional compounds on the table do not have F039 nonwastewater concentration limits. These compounds were included in the table because the F039 list may be revised in the future to include concentration limits for them, and, if it is, we want sources to analyze their combustion residues for them. However, without a current F039 concentration limit, analysis of these compounds in combustion residues would be futile because they do not have established concentration limits against which to measure the testing results.

The following nine compounds on the Appendix VIII to Part 266 table entitled ''Organic Compounds for Which Residues Must Be Analyzed'' do not have F039 nonwastewater concentration limits: cis-1,4-Dichloro-2-butene; Bromochloromethane; Bromoform; Bromomethane; Methylene bromide; 2,4,6-Trichlorophenol; o-Nitrophenol; o-Chlorophenol; and, 2,6-Toluene diisocyanate. Today's rule amends the table by including a note to the table that states testing is required for only those organic compounds for which an F039 nonwastewater concentration limit is identified.

IV. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. Because the agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, see section VI below, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. This rule also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

This technical correction action does not involve technical standards; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The rule also does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996). EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). EPA's compliance with these statutes and Executive Orders for the underlying rule is discussed in the June 19, 1998 **Federal Register** notice.

V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of November 19, 1999. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

VI. Immediate Effective Date

EPA is making this rule effective immediately. The rule adopts amendments which are purely technical in that they correct mistakes which are clearly inconsistent with the Agency's stated intent. Comment on such changes is unnecessary within the meaning of 5 U.S.C. 553(b)(3)(B). For the same reasons, there is good cause to make the rule effective immediately pursuant to 5 U.S.C. 553(d)(3).

List of Subjects

40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

40 CFR Part 261

Hazardous waste, Recycling, Recordkeeping and reporting.

40 CFR Part 266

Environmental protection, Energy, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

Dated: November 15, 1999.

Michael Shapiro,

Principal Deputy Assistant Administrator.

For the reasons set forth in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart EEE—National Emission Standards for Hazardous Air Pollutants From Hazardous Waste Combustors

2. Section 63.1210 is amended by revising paragraph (b)(1)(ii) introductory text, (b)(1)(ii)(A), (b)(1)(ii)(B) and (b)(1)(iv) introductory text to read as follows:

§ 63.1210 What are the notification requirements?

* * * * *

(b) * * *

(1) * * *

(ii) As applicable to each source, information on key activities and

estimated dates for these activities that will bring the source into compliance with emission control requirements of this subpart. The submission of key activities and dates is not intended to be static and you may revise them during the period the NIC is in effect. You must submit revisions to the Administrator and make them available to the public. You must include the following key activities and dates:

(A) The dates by which you will develop engineering designs for emission control systems or process changes for emissions;

(B) The date by which you will commit internal or external resources for installing emission control systems or making process changes for emission control, or the date by which you will issue orders for the purchase of component parts to accomplish emission control or process changes.

* * * * *

(iv) If you intend to comply, but will not stop burning hazardous waste by October 1, 2001 a certification that:

* * * * *

3. Section 63.1211 is amended by revising paragraph (b) to read as follows:

§ 63.1211 What are the recordkeeping and reporting requirements?

* * * * *

(b) *Compliance progress reports associated with the notification of intent to comply.* (1) *General.* If you intend to comply with the emission standards and operating requirements of this subpart, then not later than October 1, 2001, you must comply with the following, unless you comply with paragraph (b)(2)(ii) of this section:

(i) Develop engineering design for any physical modifications to the source needed to comply with the emission standards of this subpart;

(ii) Submit applicable construction applications to the Administrator; and

(iii) Document an internal or external commitment of resources, i.e. funds or personnel, to purchase, fabricate, and install any equipment, devices, and ancillary structures needed to comply with the emission standards and operating requirements of this subpart.

(2) *Progress Report.* (i) You must submit to the Administrator a progress report on or before October 1, 2001 which contains information documenting that you have met the requirements of paragraph (b)(1) of this section. This information will be used by the Administrator to determine if you have made adequate progress towards compliance with the emission standards of this subpart. In any evaluation of adequate progress, the Administrator may consider any delays in a source's progress caused by the time required to obtain necessary permits from governmental regulatory agencies when the sources have submitted timely and complete permit applications.

(ii) If you intend to comply with the emission standards and operating requirements of this subpart, but can do so without undertaking any of the activities described in paragraph (b)(1) of this section, you must submit a progress report documenting either:

(A) That you, at the time of the progress report, are in compliance with the emission standards and operating requirements; or

(B) The steps you will take to comply, without undertaking any of the activities listed in paragraphs (b)(1)(i) through (b)(1)(iii) of this section.

(iii) If you do not comply with paragraphs (b)(1) or (b)(2)(ii) of this section, you must stop burning hazardous waste on or before October 1, 2001.

(3) *Schedule.* (i) You must include in the progress report a detailed schedule that lists key dates for all projects that will bring the source into compliance with the emission standards and operating requirements of this subpart for the time period between submission of the progress report and the compliance date of the emission standards and operating requirements of this subpart.

(ii) The schedule must contain anticipated or actual dates for the following:

(A) Bid and award dates, as necessary, for construction contracts and equipment supply contractors;

(B) Milestones such as ground breaking, completion of drawings and specifications, equipment deliveries, intermediate construction completions, and testing;

(C) The dates on which applications will be, submitted for operating permits or licenses;

(D) The dates by which approvals of any permits or licenses are anticipated; and

(E) The projected date by which you expect to comply with the emission standards and operating requirements of this subpart.

(4) *Notice of intent to comply.* You must include a statement in the progress report that you intend or do not intend to comply with the emission standards and operating requirements of this subpart.

(5) *Sources that do not intend to comply.* (i) If you indicated in your NIC your intent not to comply with the emission standards and operating requirements of this subpart and stop burning hazardous waste prior to submitting a progress report, or if you meet the requirements of § 63.1206(a)(2), you are exempt from the requirements of paragraphs (b)(1) through (b)(4) of this section. However, you must submit and include in a revised NIC the date on which you stopped burning hazardous waste and the date(s) you submitted, or plan to submit RCRA closure documents.

(ii) If you signify in the progress report, submitted not later than October 1, 2001, your intention not to comply with the emission standards and operating requirements of this subpart, you must stop burning hazardous waste on or before October 1, 2001 and you are exempt from the requirements of paragraphs (b)(1) through (b)(3) of this section.

* * * * *

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation of part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y), and 6938.

2. In § 261.38 Table 1 is amended by revising the entry for ''Antimony, total'' under the heading Metals to read as follows:

§ 261.38 Comparable/Syngas Fuel Exclusion.

* * * * *

TABLE 1 TO § 261.38 DETECTION AND DETECTION LIMIT VALUES FOR COMPARABLE FUEL SPECIFICATION

Chemical name	CAS No.	Composite value (mg/kg)	Heating value (BTU/lb)	Concentration limit (mg/kg at 10,000 BTU/lb)	Minimum required detection limit (mg/kg)
* * *	*	*		*	*
Metals:					
Antimony, total	7440–36–0	ND			12
* * *	*	*		*	*

* * * * *

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND HAZARDOUS WASTE MANAGEMENT FACILITIES

1. The authority citation for Part 266 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3004, 6905, 6906, 6912, 6922, 6924, 6925, and 6937.

2. The Appendix VIII table to Part 266 is amended by adding the note after the table to read as follows:

Appendix VIII Table to Part 266—Organic Compounds for Which Residues Must Be Analyzed

* * * * *

Note to the table: Analysis is not required for those compounds that do not have an established F039 nonwastewater concentration limit.

[FR Doc. 99–30235 Filed 11–18–99; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Parts 10 and 15

[USCG–1999–6224]

RIN 2115–AF23

Licensing and Manning for Officers of Towing Vessels

AGENCY: Coast Guard, DOT.

ACTION: Interim rule with request for comments.

SUMMARY: The Coast Guard establishes requirements for licensing mariners who operate towing vessels, whether inspected or uninspected. This interim rule creates new licenses with levels of qualification and with enhanced training and operating experience, including practical demonstrations of skill; it also ensures that all towing vessels will be manned by officers holding licenses specifically authorizing their service. It should improve navigational safety for towing vessels. Please note that the interim rule is identified by a new docket number, because the docket for this rulemaking has been transferred to the Department of Transportation docket which can be reviewed on the Internet. To comment on the interim rule, follow the procedures described in the **ADDRESSES** section.

DATES: This interim rule is effective November 20, 2000. Comments and related material must reach the Docket Management Facility on or before February 17, 2000. Comments sent to the Office of Management and Budget (OMB) on collection of information (OMB Control No. 2115–0623) must reach OMB on or before January 18, 2000.

ADDRESSES: To make sure your comments and related material are not entered more than once in the docket, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility (USCG–1999–6224), U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(2) By hand delivery to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) Electronically through the Web Site for the Docket Management System at http://dms.dot.gov.

You must also mail comments on collection of information to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, ATTN: Desk Officer, U.S. Coast Guard.

The Docket Management Facility maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: For questions on this rule, contact Lieutenant Commander Luke Harden, Office of Operating and Environmental Standards (G–MSO), 202–267–0229; e-mail LHarden@comdt.uscg.mil. For questions on viewing or submitting material to the docket, call Dorothy Walker, Chief, Dockets, Department of Transportation, telephone 202–366–9329.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [USCG–1999–6224], indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by mail, delivery, fax, or electronic means to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request

for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

On June 19, 1996, we published a notice of proposed rulemaking (NPRM) in the **Federal Register** (61 FR 31332). In preparing this interim rule, the Coast Guard decided to place this project within the Department of Transportation Docket Management System. This administrative shift makes the material used to develop this rule more available to the public. Although it also changes the docket number, it does not alter the fact that this is the same rulemaking begun under Docket Number CGD 94–055. Please follow the procedures outlined in **DATES** and **ADDRESSES** when submitting comments on this rule. The NPRM proposed updates to the licensing, training, and qualifications of operators of towing vessels to reduce marine casualties. A more detailed treatment of the following matters appeared in the preamble to the NPRM.

The NPRM was an essential part of a comprehensive initiative undertaken by us to improve navigational safety for towing vessels. It followed our report directed by the Secretary of Transportation, entitled ''Review of Marine Safety Issues Related to Uninspected Towing Vessels'' (''the Review''). The Review identified improvements in licensing, training, and qualifications of operators of uninspected towing vessels (OUTVs) necessary to improve safety.

As the NPRM stated, the Secretary of Transportation had initiated the Review after the allision in September, 1993, of a towing vessel and its barges with a railroad bridge near Mobile, Alabama (''Amtrak casualty''). The National Transportation Safety Board (NTSB) had attributed this casualty, at least in part, to the Coast Guard's failure to establish higher standards for the licensing of inland operators of towing vessels. The Review; a previous Coast Guard study entitled ''Licensing 2000 and Beyond'' (''Licensing 2000''); and other research had concluded that the requirements on licensing, training, and qualifications of personnel that operate towing vessels were outdated and needed improvement.

On March 2, 1994, we published a notice that announced the availability of the Review and scheduled a public meeting to seek comments on its recommendations (59 FR 10031). The meeting, on April 4, 1994, was well attended by the public and representatives from a wide range of towing interests. Public comments, both oral and written, helped shape the NPRM.

The Merchant Marine Personnel Advisory Committee (MERPAC) and the Towing Safety Advisory Committee (TSAC) addressed the towing-safety initiative as articulated in the Review. These committees and several of their working groups had created reports to address licensing and training. We also used these reports to develop the NPRM.

Note, also, that many issues pertaining to licensing and training of mariners come within the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as amended in 1995 (STCW). An interim rule (62 FR 34506 (June 26, 1997)) carries this treaty into domestic effect. This interim rule requires mariners serving on certain seagoing towing vessels to meet the requirements of STCW training, certification, and watchkeeping, as stated previously in the NPRM and SNPRM. The towing vessels affected by STCW are those that are 200 gross tons or more on domestic voyages and all towing vessels on foreign voyages. For additional discussion on the effects of STCW see our response to your comments numbered 94 through 96, found later in this preamble.

We received over 787 comment letters in response to the NPRM. Because of this response, we published a notice of intent (61 FR 66642 (December 18, 1996)) explaining that we would modify the NPRM along lines urged by public comment and the advisory committees, and would publish the changes in an SNPRM. This would afford the public an opportunity to comment on the changes before issuance of a final rule. We published the SNPRM on October 27, 1997 (62 FR 55548).

During February, 1998, we also held four public meetings: in Memphis, TN; Houston, TX; Boston, MA; and Seattle, WA. We held them to receive additional views on the licensing issues in the proposed rule. The *Discussion of Comments and Changes*, next, incorporates the concerns of the meetings' attendees.

We are publishing this interim (instead of a final) rule so—

1. We can address the 114 comment letters we received in response to the SNPRM;

2. We can address the concerns of the public meetings' attendees;

3. The public can respond to changes arising from those letters and concerns; and

4. We can fulfill our commitment to the members of the towing community by providing them another opportunity to comment on our proposed changes to the licensing regulations.

Discussion of Comments and Changes

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Apprentice Mate (Steersman)

(1) One comment stated that direct supervision of the apprentice mate may be costly to small businesses.

The direct supervision would ensure the highest level of training. This interim rule formalizes the current and ''best'' practices for training. As we explain in *Small Entities*, later in the preamble, we expect the increase in costs to small businesses to be minimal.

(2) One comment questioned whether the Coast Guard regards apprentice mates (steersmen) as additional crew rather than as deckhands with added responsibility.

The apprentice mate (steersman), if any, is not a member of the crew required by the rules on manning in 46 CFR part 15. An apprentice mate (steersman) may be a deckhand working towards licensure. However, the decision how to bring mariners along as licensed personnel, and even the decision whether to bring them along, will still reside with employers.

(3) Two comments noted that the new license appears to be a form of the first-class pilot's license and suggested reinstating the system of first-class pilots.

Mariners should not confuse any new license brought about by this rule with a first-class pilot's license. Not only are the requirements different; the authority to issue a first-class pilot's license is

limited by route, which might not include any of the Western Rivers.

(4) Two comments suggested that the step of apprentice mate (steersman) in the mariner's career path is unnecessary.

The new step in the licensing structure ensures that the mariner gets the most out of training. The mariner will see the greatest benefits from training through the practical application of the knowledge required to pass the written exam for apprentice mate.

(5) One comment suggested that only the master, not the mate (pilot), should train the apprentice mate (steersman).

We agree that the master is probably the best trainer in most circumstances. However, we concluded that the mate (pilot) standing the back watch is also qualified to operate the vessel and that he or she may be a better trainer in some cases. Limiting the training to only the master could hamper it, since the master can be on duty for only 12 hours a day.

(6) Several comments noted that the SNPRM did not address the operators of harbor tugs. They recommended that the licensing structure for these operators comprise two steps, apprentice mate and master, and a 90-day familiarization period for local operations of harbor tugs.

Harbor tugs—working in what is now ''harbor assist''—do not usually have a back watch, which limits or eliminates the opportunity to operate under the authority of the mate (pilot) license. After reviewing TSAC's recommendation on the subject and considering the way this issue was addressed in the SNPRM, we changed the licensing structure proposed for vessel assist—now ''harbor assist''—to require an apprentice mate (steersman) license before advancing to master of harbor assist. The SNPRM proposed a two-step structure that skipped the apprentice mate (steersman) license. The process instated here will restrict a master's license to harbor assist.

(7) Several comments stated that the 12 months of service after the completion of the service exam is unreasonable and that this requirement would create a burden on the industry. The comment also proposed a less-stringent level of testing for the apprentice mate (steersman) license.

We disagree. Under the current licensing system for operators of uninspected towing vessels, a mariner may begin operating the vessel after passing the appropriate examination and showing 36 months service on towing vessels. In this rulemaking, a mariner may be placed in charge of the navigation of the towing vessel, as a mate, after showing 30 months service. We believe that mariners will receive more thorough and effective training operating a vessel during the 12-month period after passing the exam for apprentice mate (steersman) license and obtaining the mate (pilot) license.

(8) One comment asserted that the would-be apprentice mate (steersman) already undergoes testing on those subjects listed in Table 10.910–2.

We disagree. Table 10.910–2 outlines the subjects that the candidate for apprentice mate (steersman) will be required to have knowledge. We want the apprentice mate (steersman) to have passed that exam, then to use this knowledge in the time before applying for his or her license as mate (pilot), which allows standing of the back watch.

Assistance Towing

(9) One comment stated that an endorsement for assistance towing is necessary.

We already require an endorsement for assistance towing on a license other than a towing license. The lesser included authority will remain for masters of towing vessels and for masters or mates authorized service on inspected vessels over 200 gross tons, with licenses endorsed for towing.

(10) One comment suggested that the Coast Guard should license mariners performing either assistance towing or towing for hire.

We do license assistance towers to engage in assistance towing.

(11) One comment recommended that we keep assistance towing separate from the operation of uninspected towing vessels.

We do.

(12) Two comments requested that the Coast Guard clarify the term ''assistance towing'' so it is clear who is exempt.

Sections 10.103 and 15.301(a) define ''assistance towing.'' This interim rule defines ''disabled vessel'' to clarify the relation of assistance towing to disabled vessels.

Company Responsibility

(13) One comment suggested that the Coast Guard clarify that the requirements for a towing vessel do not apply to an inspected passenger vessel that serves as a propelling vessel for an inspected passenger barge.

In this scenario, the master of the inspected passenger vessel would hold lesser included authority to operate a towing vessel. This interim rule does require the master of the inspected passenger vessel to hold a towing endorsement on his or her license.

Cost

(14) One comment asked whether the cost of traveling to the REC is included in the Regulatory Evaluation. Another stated that mariners do not have the luxury of planning ahead for an appointment with the REC, given the schedules of some towing jobs.

We did not include the cost of traveling to the REC in the Evaluation, because we cannot determine it: Mariners need go to specific RECs only when their licenses are geographically limited and the local OCMIs must decide whether to grant limited licenses. Current license-holders can renew by mail, if they provide the necessary documents, and can thereby eliminate trips to the RECs. This rulemaking does not change the 5-year validity of a license.

(15) One comment requested that the Coast Guard specify the exact cost of reviewing a license.

46 CFR 10.109 lists the fees charged for transactions concerning licenses. From time to time, by notice-and-comment rulemaking, the Coast Guard adjusts these fees so that they cover the actual costs to the Coast Guard of rendering the services. See current rulemakings [64 FR 42812 (August 5, 1999) and 64 FR 44786 (August 17, 1999)] adjusting fees charged for license transactions.

(16) One comment pointed out that, unless mariners are grandfathered into the new licensing structure, small businesses will lose considerable revenue while some will go out of business.

We will grandfather mariners, with current licenses for OUTV, as master or mate (pilot) of towing vessels. There probably will not be a large number of mariners with licenses as second-class OUTV who will need to renew their licenses as mate (pilot) of towing vessels.

(17) One comment argued that the impact on small businesses is greater than the SNPRM stated. It continued that companies will have difficulty completing the increased paperwork and finding employees with the increased experience.

The experience required will not affect the mariners who already hold their OUTV licenses. The analyses in the preamble of this interim rule treat the impacts of this interim rule on small businesses, in terms of both monetary costs and paperwork.

Definitions

(18) One comment requested that the Coast Guard inform mariners that the definitions, which were removed from

this rulemaking and were included in the one on STCW, still apply to 46 CFR parts 10 and 15, as appropriate.

The NPRM in this rulemaking proposed definitions for ''Coast Guard-accepted,'' ''designated examiner,'' ''practical demonstration,'' ''qualified instructor,'' and ''standard of competence,'' which were incorporated into 46 CFR parts 10 and 15 (and 12) as appropriate by the rulemaking on STCW. Since the definitions were and continue to be in effect, it was unnecessary to include them in the SNPRM for this rulemaking, and it is unnecessary to include them in this interim rule.

(19) One comment suggested that the RECs receive guidance on the terms ''mate'' and ''pilot.'' It also asked how the terms will appear on licenses and what term will apply to mariners on the Great Lakes. Two comments recommended that a licensed officer not be called a mate, which traditionally refers to a deck hand.

The licensing requirements for mate and pilot of towing vessels will be the same. The mariner applying for the license can decide on the title, mate or pilot. The mariner should keep in mind that, if he or she changes the area of operation, the title may not be appropriate and may entail a fee to have it changed on his or her license.

(20) Several comments requested that the Coast Guard clarify the term ''unlimited.'' Two comments stated that the words ''less than 200 gross tons'' may lead to confusion.

The term ''unlimited'' appears in §§ 10.464 and 10.465 of the SNPRM only to distinguish between restricted licenses and others. Therefore, licenses for towing vessels will not bear ''unlimited'' endorsements, and we have removed that term from this rule. Omission of the term will imply that the licenses are not restricted to harbor assist or to local geographical areas. Also, to eliminate confusion, we have removed the phrase ''less than 200 gross tons.''

(21) One comment asked whether the term ''assistance towing'' would confine the mariners to one barge at a time.

''Assistance towing'' already carries a definition in the rules, and this rulemaking is not changing it; however, this rulemaking also contains a definition of ''disabled vessel'' that clarifies the former definition of ''assistance towing''. Towing barges does not constitute assistance towing, since barges, by definition, never move under their own power.

(22) One comment recommended not amending the terms ''captain,'' ''mate,'' and ''pilot.''

We are not changing the term ''captain.'' However, a mariner could choose either ''mate'' or ''pilot'' depending on the area in which he or she operates. For example, a mariner licensed for oceans would probably choose the term ''mate'' of towing vessels, while a mariner licensed for Western Rivers would probably choose the term ''pilot'' of towing vessels.

(23) Many comments noted that a private company owns the trademark rights to the term ''vessel assist.'' Another comment suggested the term ''commercial assist'' to replace the term ''vessel assist.'' Yet another stated that the term ''vessel assist'' is easy to confuse with ''assistance towing.''

We agree that ''vessel assist'', whether or not it conflicts with commercial usage of the term, sounds too much like ''assistance towing.'' Therefore, we are changing ''vessel assist'' to ''harbor assist.''

(24) One comment requested that the Coast Guard define ''accepted training course.''

There is already a definition of *Coast Guard-accepted,* which applies to training courses, in § 10.103.

Demonstration of Proficiency

(25) Several comments suggested that the Coast Guard require check-rides to demonstrate proficiency only for mariners charged with negligence or violation of statute or rules. Other comments stated that a check-ride demonstration should apply only for new licenses.

We agree that new mariners in the towing industry must demonstrate proficiency before being authorized to operate the back watch. We maintain that requiring a demonstration of proficiency for mariners who have had action taken against their license and for all applicants for new licenses is one of the best methods to prevent marine casualties.

(26) One comment asked the Coast Guard to provide a more complete explanation of the one-half hour of management time required of mariners performing a final check-ride.

This is simply the time the master or mate needs to prepare the final check-ride report or document (that was filled out by the Designated Examiner) for delivery to the REC.

(27) Several comments stated that check-rides are unnecessary for holders of OUTV licenses. They suggested that a company letter or a mariner's record of performance should be sufficient as proof of proficiency. One comment suggested that a company letter demonstrating service, not navigational proficiency, should be all such a mariner needs for license renewal.

We expect that no requirement of demonstration of proficiency for current holders of OUTV licenses will be necessary. However, unless these holders furnish documentation of proficiency during the validity of their current licenses, we may require a demonstration of proficiency before renewal of their licenses.

(28) One comment noted that proficiency-testing imposes an economic burden on license holders. This comment recommended that companies maintain records of proficiency.

We strongly encourage companies to maintain record of proficiency, but the mariners have their own responsibility to maintain records of the training received and experience demonstrated during the validity of their licenses.

(29) One comment recommended that the Coast Guard allow trip pilots to submit daily logs rather than undergo check-ride demonstrations.

If a daily log includes training received and drills held, such as man-overboard and fire drills, it certainly can be part of the documentation necessary to demonstrate proficiency.

(30) One comment requested that the Coast Guard clarify the qualifications of the persons administering the check-rides.

The persons administering the check-rides will be designated examiners as defined in the current rules and in Navigation and Vessel Inspection Circular (NVIC) 6–97. To become a designated examiner, a person must produce documentary evidence that he or she—

(a) Has experience or training, or received instruction in assessment techniques;

(b) Is qualified in the task for which the assessment is being conducted; and

(c) Holds the appropriate level of license, endorsement, or other professional credential suitably related to the area of assessment.

Designated Examiners

(31) One comment noted the difficulty in assessing an individual's ability in one opportunity to demonstrate proficiency. The captain of a vessel is in a better position to assess someone's abilities, since he or she can observe a person's performance over time.

The captain and mate (pilot) will be integral parts of a mariner's training. Yet the designated examiner will observe such practical proficiency as may be the result of their training of the mariner.

(32) One comment recommended that the Coast Guard ensure that the

designated examiner implements the examination process fairly.

We will ensure this, as much as possible, and also that the training and evaluation of mariners are consistent.

(33) Many comments recommended that the Coast Guard clarify the qualifications and the selection process for designated examiners. One comment recommended that every examiner should hold a master's license.

We will thoroughly evaluate the application of a would-be examiner before we issue a letter of approval. Again, we recognize that the captain (master), in most cases, may be the most qualified to conduct the training leading up to the demonstration of proficiency but that he or she may not desire to be an examiner.

(34) One comment suggested using designated examiners only for new or suspended licenses.

This interim rule does require examiners for new or suspended licenses; but we may also require a check-ride with an examiner, if the documentation for renewal is not sufficient (see § 10.209 in the regulatory text of this interim rule).

(35) Several comments suggested that the Coast Guard train, select, and qualify designated examiners so that these processes are free from corporate influence. One comment suggested that each examination should involve two examiners, one from the Coast Guard and one from the company.

We see the merit in this concept, but we want companies to take more responsibility for this process. Our goal is to empower the companies to seek out, from their own ranks, mariners who possess the ability to become designated examiners. Although the suggestion of having two examiners appears to be a good concept, it would be excessive and cost-prohibitive to the mariner and the industry.

(36) One comment recommended that the Coast Guard clarify how the designated examiners conduct their assessments.

This issue is complex because there are so many different types of ''towing'' within the industry. The examiners would have to tailor the demonstration of proficiency (check-ride) to the specific experience and training of the mariner for the route and type of towing.

(37) One comment noted the problem of finding a designated examiner with the wide range of experience required to assess people in an industry that requires diverse skills and experience.

We agree that an examiner who could assess mariners in all facets of the industry would not be easy to find. For this reason, the Coast Guard will issue examiners' certificates for certain portions of the industry. (For this reason, too, companies should furnish their own examiners.) This would not preclude a mariner from being an examiner for more than one portion or even for all portions of the industry, but we expect that any one examiner would specialize in one or a few portions, such as harbor assist, fleeting, long-line, or river towing (this last usually associated with pushing ahead).

(38) Two comments approved of a company-designated examiner. One comment stated that such an examiner will have more of a vested interest in ensuring that a mariner is qualified than will a Coast Guard examiner.

We expect this to be true in most cases, which is consistent with the concept of empowering both the company and the mariner.

General

(39) One comment stated that towing on brown and towing on blue waters should fall under distinct regulatory regimes.

Towing on the two routes does differ in some respects. The navigation requires the use of different charts, from the Army Corps of Engineers and the National Oceanic and Atmospheric Administration, respectively. But it does not differ so much as to make distinct regimes advisable.

(40) One comment suggested that the Coast Guard determine whether it is necessary to exempt towing vessels of less than 200 gross tons engaged in mining minerals and drilling oil.

Under 46 U.S.C. 8905(b), the requirement that a towing vessel be operated by a licensed individual does not apply to towing vessels of less than 200 gross tons engaged in the offshore exploitation of minerals and oil, if the vessels have sites or equipment serving the offshore mineral and oil industry as their places of departure or their ultimate destinations.

Grandfathering of Licenses

(41) We received 18 comments concerning the grandfathering of existing licenses. Most of the comments requested information on the process and requirements for current holders of licenses to obtain licenses under the new license structure. Several comments suggested that the Coast Guard ensure that the mariners have the required experience and familiarity of routes before grandfathering their licenses.

Current holders of OUTV and second-class OUTV licenses will not have to get new licenses until they either upgrade or renew these licenses. At that time, we will issue their licenses as master or mate (pilot) of towing vessels. When a mariner renews his or her license as master or mate of vessels of appropriate gross tonnage or as first-class pilot holding an endorsement on his or her license for towing vessels, we will endorse the new license for towing vessels, if the holder can prove recent towing service. In the towing industry, this documentation is the only way we can ensure that the mariners have the required experience and familiarity of routes for renewal of their licenses. We cannot depend on shipping articles, discharges, and official logbooks to verify experience, because they are not required on most towing vessels. Of course, when vessels keep them anyway, we may use them to verify experience.

(42) Two comments suggested that the Coast Guard specify which mariners may be grandfathered. For example, one comment recommended that the Coast Guard renew the licenses of masters of vessels 100 gross tons or less.

Holders of OUTV licenses will receive licenses as master of towing vessels upon renewal. Holders of licenses as master of inspected, self-propelled vessels, or as mate or pilot of inspected, self-propelled vessels of more than 200 gross tons, will receive the same license and an endorsement for towing vessels if they are operating in the towing industry. We do not anticipate renewing any second-class OUTV licenses, since the mariners holding these licenses should be eligible for licenses as master of towing vessels by the time their licenses expire.

(43) Two comments recommended that the Coast Guard clarify how the mariner will prove prior deck service when there is currently no guidance for the Regional Examination Centers (RECs) and when previous employers have gone out of business or have been consolidated.

The towing officers' assessment record may be a valuable tool to overcome this problem by documenting vessels and dates, along with any records of employment or training the individual mariner may keep.

(44) Several comments agreed that at least 18 months of prior deck service for the mate (pilot) is a good requirement. Two comments suggested that the 18 months should be extended to 36 months. One comment suggested that even the 18 months was too burdensome on the mariner.

We recognize the support of the 18 months of service for a mate (pilot), but disagree with the suggestion that it be extended to 36 months. We do not want

to overburden the new mariners coming into the towing industry. However, the intent of this rulemaking is to increase the level of safety; therefore, we are adopting the 18 months of service as proposed in the SNPRM.

(45) One comment requested that the Coast Guard clarify the term ''on deck.''

We consider ''on deck'' to indicate working in the deck department as opposed to in the engineering or steward's department.

(46) Two comments noted that the requirement of 1 year of sea service as a mate (pilot) before the Coast Guard issues a master's license could place a burden on small companies or affect the availability of licensed personnel.

This requirement equates to the current one for a second-class OUTV license. We now authorize anyone holding this license to stand the back watch. Small companies are already investing time and effort to develop OUTVs. Making the step process mandatory for new licenses will improve that process by providing milestones toward obtaining the license as master of towing vessels.

(47) One comment suggested that the Coast Guard accept or give partial credit for service on tugs of less than 26 feet.

We disagree. While the legal definition of a towing vessel (46 U.S.C 2101(40)) does not specify a minimum length, the licensing-and-manning statute (46 U.S.C. 8904(a)) states that a licensed individual must operate a towing vessel that is at least 26 feet in length. To ensure that the experience is comparable, we established the minimum length of 8 meters (26 feet).

(48) Several comments requested that the Coast Guard explain the relationship and differences between the training-record book required under STCW and the one proposed in the NPRM.

The training-record book required by STCW is not as flexible as the towing officers' assessment record required by this interim rule for towing vessels; therefore, for an original license as mate (pilot) of towing vessels you can not substitute an STCW training-record book for the towing officers' assessment record nor can you substitute the towing officers' assessment record for the STCW training record book. For example, all requirements for STCW must be met to get an STCW endorsement; whereas, if the license need not bear an STCW endorsement (as, for example, it need not for towing inland), the towing officers' assessment record need only attest proficiency in the kind of towing the mariner is working in.

(49) One comment asked the Coast Guard to clarify the ''unlimited'' section of the towing officers' assessment record.

The assessment record does not have an ''unlimited'' section. But, if you completed all the sections of the assessment record and demonstrated proficiency in all the different types of towing, we would not limit you to any one type of towing.

(50) Many comments stated that the towing officers' assessment record would be a good tool to track the experience of each mariner, but several requested that the Coast Guard provide a more complete discussion of the requirements for maintaining the assessment record. The comments raised questions like, ''What entries are included?'' and ''Will there be a phase-in period?''

We require, for demonstration of proficiency, entries that have the footnote ''All'' and the footnotes for a particular route desired: ''O'' for oceans, ''C'' for coastwise and near-coastal, ''I'' for inland and Great Lakes, ''WR'' for Western Rivers and ''R'' for rivers. Moreover, the assessment record will allow space to enter the vessels served on, dates served, routes, drills participated in, and all training received. As this rule is effective on November 20, 2000, the phase-in period is 1 year.

(51) Several comments requested that the Coast Guard keep the requirements of the assessment record simple and standardized. One comment noted that a standardized format would assist the RECs in the review process.

We will standardize the assessment records as much as possible and clearly identify the requirements. However, as mentioned earlier in this section, the type of towing that the vessels are engaged in will determine what other items need to be addressed. Before the effective date of the interim rule, we will develop guidance for the RECs to standardize the assessment records' evaluations.

(52) Several comments stated that a towing officers' assessment record would impose a paperwork burden on the mariners. One comment suggested that the vessel's daily log should fulfill the requirements of this rulemaking.

We address the paperwork burden under *Costs*, within *Regulatory Evaluation*, and under *Collection of Information* later in the preamble. We agree that a vessel's daily log could aid the mariner in keeping track of his or her experience; but such logs are not required on most towing vessels. If the vessel keeps such a log, the mariner may use it.

(53) Two comments recommended that the captain of the vessel, not the employer, verify the information in the towing officers' assessment record.

While the master is the best person to verify completion of tasks in the assessment record, companies have to work with the captain to ensure that mariners get appropriate credit for experience gained during underway time. Cooperation between companies and captains is also consistent with the Review's recommendation that companies assume more responsibility for the training of their crews.

(54) One comment noted that it would take longer than 1 hour over a 3-year period to learn and comply with the requirements of this rulemaking.

The 1 hour referred to is only for filling out the paperwork, and is an average estimated for all licensed OUTVs.

(55) One comment stated that there would be a burden on employers to maintain records for each mariner.

We determined that companies are already gathering the required information for other purposes such as pay, benefits, and billing for services rendered; therefore, records maintenance should not be an added burden to the employers.

(56) Two comments stated that this rule imposes confusing paperwork requirements, which will be a great burden on the mariner.

We will make guidance available to all OUTVs and prospective masters and mates (pilots) of towing vessels to keep the recordkeeping as simple as possible.

Horsepower

(57) Two comments supported regulating according to horsepower (HP) ''breakpoint'' even though one of them noted that the ratio of HP to barge does not hold true all the time. Two comments recommended that the Coast Guard restrict the tons towable with a given HP, lest companies overload or overwhelm the available HP.

This is not feasible, as we mentioned earlier, because of the different combinations of tows—especially on the rivers. If companies overload or overwhelm available HP, they risk considerable losses, which create an incentive to be sensible in their arrangement of barges.

(58) One comment recommended a breakpoint of 5,000 HP, if the Coast Guard persisted in regulating according to HP.

Since we have forgone any attempt to regulate, the point is moot.

Public Input

(59) Nineteen comments stated that the Coast Guard should receive more input from the mariners. Many

requested that the Coast Guard find better ways to inform mariners of proposed changes to rules. Word of these changes must reach the mariners with enough time for them to get involved in the regulatory process. Two comments suggested that the Coast Guard establish direct contact with the working mariners, by a master mailing-list or database of concerned mariners. Several comments pointed out that late notice of public meetings did not allow mariners to adjust their schedules to attend the meetings.

We encouraged input from active mariners. The NPRM drew 787 comment letters; the SNPRM, just 114. The dramatic decrease is due precisely to the fact that the SNPRM responded to the comments on the NPRM from the public. We provide up-to-date information by the Internet; the Marine Safety Newsletter; press releases; and responses to telephone, fax, and written inquiries.

(60) Four comments asked the Coast Guard to extend the comment period.

We are publishing this interim rule with a request for comments before a final rule so the public will have an opportunity to express their views on the latest changes. Publishing this interim rule between the SNPRM and final rule is equivalent to extending or reopening the comment period for 90 days.

Refresher Courses and Training

(61) Many comments favored the refresher courses on Rules of the Road and suggested implementing the requirement every 5 years, at the same time as license renewal and radar re-certification.

Combining the radar-observer course and the courses on Rules of the Road could streamline the renewal process; however, we will not require the combination of these courses. It is not appropriate for us to micro-manage the delivery of courses, even if our rules separately require them.

(62) One comment asked how the Coast Guard plans to administer the refresher courses.

We do not plan to administer the refresher courses ourselves. We will review, accept or approve, and oversee the courses administered by the industry.

(63) One comment asked whether the Coast Guard requires exercises on Rules of the Road for everyone renewing a license.

No, the current rules require exercises on Rules of the Road for renewing a license for master or mate (pilot) of towing vessels, only when a mariner presents evidence of employment in a position closely related to the operation, construction, or repair of vessels as discussed in 46 CFR 10.209(c)(1)(iv).

(64) Two comments opposed refresher courses and suggested that mariners with decades of experience do not need such courses.

This interim rule does not require refresher courses for renewal of licenses where the mariner can document continued service, training, and demonstration of proficiency. It requires the courses only when the mariner cannot document those three. For example, a mariner, who not worked in the towing industry for long periods of time, would have difficulty documenting service, training, and demonstration of proficiency.

(65) Several comments recommended ways to conduct the courses and training. One comment recommended personal-computer-based, or interactive, training. One suggested that the courses be in-house courses or open-book tests to take at home. Two suggested that the Coast Guard avoid take-home and mail-in exams and establish renewal classes annually or biannually. Some suggested including radar re-certification in the refresher courses. Others stated that no radar course is needed.

We have not ruled out computer-based training as part of an accepted or approved course. An in-house course, meaning one given at a company's facility, is a possibility. Take-home with mail-in completion is not an option for radar training. However, there could be an on-going process during the term of validity of the license to document proficiency for renewal. Annual and biannual courses would be cost-prohibitive and excessive. The Coast Guard will continually evaluate each course for compliance with the requirements for refresher courses and radar training.

(66) One comment disputed the applicability of § 10.309 to personnel of domestic towing vessels exempted from STCW.

The requirements in § 10.309 cover training for all licenses subject to STCW. While this section indeed does not apply to licenses that do not require STCW certificates or endorsements, it is an excellent generic description of a Coast Guard-accepted training course and may be used as a guide for developing Coast Guard-accepted training courses exclusively for (non-STCW) towing-vessel licenses.

(67) One comment noted that approval of training other than through courses would impose a great burden on the Coast Guard.

Training other than through courses already comes within the rules and will stay there through this interim rule. We intend for such training to serve the towing industry. It may in fact increase the burden on us.

(68) One comment recommended that the Coast Guard establish clear criteria for the approval of training.

Section 10.302 already contains clear criteria for the approval of training, and the National Maritime Center evaluates them from time to time.

(69) One comment stated that training other than through courses is unnecessary. Another noted the difficulty of finding trainers who are able to train mariners with decades of experience.

We have determined that the training is necessary, especially for mariners new to the towing industry. It is not normally necessary for mariners with decades of experience; these mariners just need to be informed of recent changes.

Regional Examination Centers (RECs)

(70) Many comments stated that the RECs are overworked and will not be able to handle the workload created by the new rules.

We acknowledge that this is a concern for mariners and the industry; however a full examination of the program demonstrates that much of this rulemaking will add little workload to the RECs. This rule will not increase the number of examinations to be given, and will add only one level of licenses. Also, the licensing program may realize some relief due to a shift in operations of casino vessels from river to shore-side. The riverboat casino industry contributed to the work backlogs in the RECs during the mid-1990s. This ongoing shift in their operations should reduce the number of license and merchant mariner document transactions at those facilities. Incomplete mariner application packages also cause a delay in issuing licenses. The licensing process established by this rule will ensure the completeness of the mariner's application package; reducing the time between the receipt of the application and when the license is issued.

Responsibility of the Master

(71) Several comments noted that there are many conditions over which the master has no control, such as fatigue of the crew and deadlines from the company. Many of these recommended that the responsibility for the safety of the vessel needs sharing among the master, the company, and the crew. They stated that the master cannot be responsible for the independent actions of the pilot or engineer. They

asked the Coast Guard to specifically outline the master's responsibilities.

The master is responsible for the care and safety of the vessel and crew. Sharing of responsibility for safety of the vessel already occurs, and should occur; but it cannot occur equally. The owner has an investment in the vessel and cargo, and the crew has a responsibility to do its jobs as safely and efficiently as possible. There still has to be someone in charge, and that is the master. As we stated before, the stander of the back watch is responsible for his or her acts; nevertheless, if an accident happens because of acts of the back watch carried out on orders given by the master, then the master may be accountable for the orders given. Usually the company outlines the responsibilities in the conditions of employment when it hires a master. In other words, what the company expects the master to do is—within the general guidelines of maritime and other law—for the company to determine.

(72) Many comments pointed out that a master cannot be responsible for both the front and back watch. Others suggested that, if the Coast Guard enforced rules that limit a master from working over a 12-hour day, the master would be even less well-situated.

From our history of administrative hearings on suspending and revoking licenses, the OUTV has seldom been held responsible for misconduct of the back watch, unless the back watch is following an order given by the master. If the master does not stand a watch, as he or she does not aboard a lot of deep-draft seagoing vessels, he or she may fairly bear some general responsibility for all watches.

Route Endorsements

(73) Many comments requested that the Coast Guard clarify the requirements for route endorsements. They also suggested that the Coast Guard clarify the process for examination and evaluation.

A route endorsement requires an evaluation of the applicant's experience, training, and knowledge of a specific route. Information on the process of examination and evaluation for original licenses and renewal of existing licenses appears in 46 CFR part 10. (This information, including printable forms, is also available on the Internet through some of the RECs. You may access these sites at http://www.uscg.mil/hq/g-m/marpers/pers.htm.) The information in part 10 comprises definition of terms, general requirements for all licenses, professional requirements for deck officers and engineer officers, and subjects of license examination.

(74) Two comments asked whether we charge user fees for route endorsements.

Yes, we charge a fee for a change in the scope of a license, as by endorsement. The required fees are administrative ones for evaluation and testing.

(75) Many comments stated that route endorsements would be too restrictive for mariners who may change routes on a moment's notice. Some stated that route endorsements would limit the employment of mariners. One comment suggested that route endorsements subordinate to the main route would constrain new businesses.

The current licensing scheme already contains route endorsements for the OUTV; these are not subordinate route endorsements. This interim rule does contain additional requirements for operating on Western Rivers, because we determined that the unique conditions encountered on those rivers warrant stricter standards.

(76) One comment opposed the requirement to demonstrate experience on routes. One disagreed with the requirement to prove experience on subordinate routes, and noted that the Coast Guard does not require the same proof for other vessels. Another stated that 90 days to qualify on a route is too long.

Other licensing schemes, such as that for oceans, demand considerable training and experience compared with that for the OUTV. Still, oceans do not have parallel shores like Western Rivers. For this reason, a master holding a license for oceans and whose initial training and experience was in excess of that required for OUTV, must have his or her license endorsed to sail on Western Rivers.

Furthermore, we are amending the definition for *Inland waters* in 46 CFR 10.103 to also exclude Western Rivers. When a master or mate of towing vessels navigates both inland and Western Rivers, both routes will have to be endorsed on his or her license. The phase-in period for the dual endorsement will be at the next renewal or issuance of a new towing license after the effective date of this rule.

(77) One comment asked whether the 90-day requirement to qualify for Western Rivers is long enough. Two comments requested that the Coast Guard extend the qualifying time for those rivers to 180 days.

We recognize Western Rivers present unique operating conditions, requiring additional time to ensure familiarity. We also recognize the value of the experience gained in navigating other routes. The mariner adding the Western Rivers endorsement to an existing license, already has demonstrated experience operating towing vessels, and will have one or more routes endorsed on his or her license. Considering this minimum time required to obtain the endorsement, and these are experienced mariners, 90 days is enough time for the purpose of this requirement.

(78) One comment opposed route endorsements for mariners with more than 5 years of experience because those mariners have worked in most areas.

We will grandfather the licenses of mariners for the routes on which they can document service. Mariners with 5 or more years of experience in the towing industry may not have been exposed to special hazards associated with unfamiliar routes. Therefore, we will not automatically consider mariners with 5 years of experience or more to be qualified for all routes.

(79) One comment asked whether Puget Sound would be split into different routes.

No, Puget Sound will remain one near-coastal route.

(80) Some comments suggested that the routes be less specific; others, that they be more specific. One comment recommended that the single Western-rivers route should be separated into a route for each river with a 30-day posting requirement for each.

Specific endorsements for rivers (''sub-routes'') would significantly increase the paperwork burden and the burden on the individual mariners without any need or benefit comparable to that for specific endorsements for routes.

(81) One comment requested clarification on why the Coast Guard needs to align licensing requirements for inland waters and Western Rivers with those under the STCW.

One of the recommendations from the Review was to reevaluate the oceans (domestic-trade) route authorized for an OUTV license and to propose alternatives that conform to international standards. This is why we accept the completed STCW training-record book as complying with the towing requirements for renewals and upgrades.

(82) One comment suggested applying tonnage restrictions only to the inland waters and Western Rivers.

We cannot manage restrictions on tonnage of the barges in a tow, because a single tow may contain fully loaded, partially loaded, and empty barges. Therefore, we will rely on the companies, who risk their barges and cargo, and on their underwriters, who stand most losses, to configure tows for safe navigation.

(83) One comment suggested that the Coast Guard require mariners with licenses endorsed for Western Rivers to have experience above the Baton Rouge Bridge on the Mississippi River.

Companies should take the responsibility to ensure that their bridge crews have experience on any section of the Western Rivers before they entrust their vessels to them for that section.

(84) One comment asked why the Coast Guard did not include the ''unlimited'' exam in Table 10.910–2.

The ''unlimited'' exam referred to by this comment is the same OUTV exam included in Table 10.910–2 under license codes 10, 11, and 12.

(85) One comment recommended that the Coast Guard specify what it will test on a limited exam. The comment stated that the terms ''partial'' and ''special'' are familiar to mariners but that ''limited'' is a new term.

We previously addressed the limited OUTV license, in the current regulations under 46 CFR 10.464(f), which stated: ''The examination for a license as operator of uninspected towing vessels endorsed for a local limited area is modified by deleting inappropriate questions.'' For example, an exam for a license limited to the port of New York may not have the same questions as an exam for a limited license for Memphis, Tennessee, because the traffic schemes are different.

Safety

(86) One comment suggested that, before the Coast Guard lets a mariner handle a larger tow, it should require him or her to serve as an apprentice mate during high and low water.

Under this interim rule the new mariner will train as an apprentice mate (steersman) before getting a license as mate (pilot). Grandfathered or not, mariners will still have to prove their competence before employers entrust them with larger tows.

Simulators

(87) Several comments agreed that simulators are a good idea, but urged that they not be used for new applicants or inexperienced pilots.

In most cases, we do not expect entry-level mariners to use simulators; however, simulators should remain an option for mariners unable to demonstrate proficiency on a towing vessel. Their use is no substitute for actual bridge time required for a mate (pilot) license.

(88) Two comments stated that simulators have no place at all in demonstrating proficiency.

We disagree. Simulators are valuable training tools in the maritime industry. They may require adjustments to make them more applicable to the towing industry, but they have their place.

(89) One comment pointed out that using simulators imposes added costs (for example, the cost of traveling to the simulator site).

Costs get a thorough examination under *Costs,* within *Regulatory Evaluation,* in the summary of our analysis that appears later in the preamble.

(90) Many comments stated that mariners can demonstrate their proficiency only in real-life situations, on towing vessels, because simulators lack the real-life pressure of towing vessels. Some comments suggested using simulators as devices to train mariners rather than as devices to test the skills of mariners.

We concluded that the best training is ''hands-on'' training aboard towing vessels; however, as we noted earlier, in testing as well as in training, simulators have a place.

(91) Two comments recommended three days of sea time for every day in a simulator.

Neither comment offered any basis for this equivalency (or any other). If someone can validate any such equivalency, we will consider it.

(92) One comment stated that simulators are invaluable and should be mandatory for training.

We agree that simulators are valuable. But making them, and only them, mandatory for training would be neither practicable nor cost-effective. Hands-on experience still delivers the best training.

(93) One comment asked why simulators persisted into the SNPRM when so many comments on the NPRM, 86 percent of the 115 comments to the NPRM on use of simulators, opposed them.

Simulators persisted into the SNPRM, and persist into this interim rule, because they are valuable tools for both training and testing. To allay some of the concerns about the use of simulators, e.g., their cost and availability, the use of simulators is optional.

STCW

(94) Several comments asked the Coast Guard to clarify how the interim rule on STCW and this interim rule on licensing and manning will affect mariners on vessels under 200 gross tons (as admeasured under 46 U.S.C. 14502 (regulatory measurement)). These comments also asked whether an STCW endorsement is necessary for a master on a vessel of less than 200 gross tons, towing a barge on a voyage to another country. The comments recommended that STCW endorsements be available to masters and mates who wish to be considered for international voyages.

We require any licensed mariner on a towing vessel of less than 200 gross tons, on a coastwise voyage (from a port in the U.S. to a port in the U.S.) to have his or her license endorsed for STCW. The mariner can get the license endorsed without added training or assessment. However, when a towing vessel of less than 200 gross tons is on a foreign voyage, all crewmembers will have to meet basic requirements of safety training and assessment under STCW.

(95) One comment requested clarification of the procedure to obtain an STCW endorsement.

That procedure is the subject of a separate rulemaking, on the implementation of STCW (62 FR 34506 (June 26, 1997)).

(96) One comment stated that adherence to existing laws, policies, and industry practices does not necessarily satisfy the requirements of STCW.

We agree that, for most mariners on towing vessels, the requirements of STCW are stricter than existing laws, policies, and practices. But those three sources provide an adequate level of safety for mariners on towing vessels.

Whistleblowers

(97) Several comments noted that there is not enough protection and incentive for mariners who expose abuse by industry. Several comments stated that employers coerce mariners to work in unsafe conditions.

This is a concern of Congress, which, again, affords some relief in 46 U.S.C. 2114. It is a concern of the Coast Guard, too, but is not within the scope of this rulemaking.

(98) One comment suggested that working groups from within industry should address the problems of coercive tactics in a different proceeding.

We agree that this is a good suggestion. TSAC may consider working groups to focus on these problems.

(99) One comment stated that a mariner may have difficulty getting a letter of service from an employer against whom the mariner has filed a complaint.

This has always been a problem when companies go out of business or there is a conflict between employer and employee. An REC usually works with a mariner to evaluate whatever records of employment the mariner alleges.

Comments Beyond the Scope of This Rulemaking

We acknowledge receipt of the following comments but consider them to be beyond the scope of this rulemaking.

(100) One comment requested that the Coast Guard streamline the renewal of licenses so that it is faster.

(101) Two comments asked whether the Coast Guard is considering towing vessels for a formal inspection program.

(102) One comment recommended that the Federal Government focus on the upkeep of channels to improve safety.

(103) One comment noted that recreational boaters threaten the safety of commercial and of other recreational vessels. Training or licensing recreational boaters would enhance safety.

(104) One comment suggested improving safety by requiring licensing or documentation for all personnel and the inspection of all vessels.

(105) One comment suggested establishing a Board of Pilots to investigate accidents, as in trucking.

(106) One comment stated that Coast Guard personnel at the National Maritime Center (NMC) lack small-vessel expertise.

(107) Several comments recommended that the Coast Guard include the Gulf Intracoastal Waterway (GIWW) in the Western-rivers and near-coastal routes. One comment specifically requested that the Coast Guard consider the Mississippi River below the Baton Rouge Bridge as part of the inland waterway. Two comments noted that much of the commerce traveling in and out of the Gulf Coast also uses the GIWW.

(108) One comment recommended that the Coast Guard state specifically what bodies of water the Western Rivers comprise. The comment noted that separation of the Western Rivers from the inland rivers causes confusion along the Gulf Coast.

(109) One comment suggested consolidating the routes for rivers and Western Rivers.

(110) One comment recommended that the Coast Guard implement safety requirements for the vessels, not for the mariners.

(111) One comment suggested that safety would improve if the Coast Guard inspected all towing vessels and licensed all their personnel.

(112) One comment noted the increase in risk to mariners with the increase in the transport of hazardous materials.

(113) Several comments suggested that towing companies focus on improving the safety of equipment. Some noted that some of the unsafe operations are due to the companies' increasing tonnages and reducing crews.

(114) One comment stated that mariners must accept the unsafe conditions offered by the companies, or the companies will hire mariners who will work in those conditions.

(115) One comment recommended that the Coast Guard ensure adequate numbers of mariners on vessels. One comment stated that the towing industry needs a program similar to the ISM Code, under which the employers could help mariners get the necessary rest by implementing three-watch rotations and increasing the manpower.

(116) Two comments stated that a company's responsibilities should include training over specific routes and restricted sailing in adverse weather.

(117) One comment suggested that the Coast Guard make companies accountable through the enforcement of civil penalties for non-compliance.

(118) One comment stated that the RECs lack the expertise to prepare local-area exams. The comment also pointed out the difficulty in preparing mariners for exams whose topics are not listed in Table 10.910–2.

Regulatory Evaluation

This interim rule is an integral part of the Coast Guard's comprehensive initiative to improve navigational safety for towing vessels. The towing-vessel industry has experienced several serious casualties in recent years, most notably the allision in September 1993 of a towing vessel and its barges with a railroad bridge near Mobile, Alabama. In this incident, barges being pushed by a towboat in dense fog displaced the Big Bayou Canot Railroad Bridge. An Amtrak train with 220 persons on board struck the displaced bridge and derailed. Forty-two passengers and 5 crewmembers were killed; 103 passengers were injured.

The National Transportation Safety Board determined that the probable cause of the derailment was the displacement of the railroad bridge when it was struck by a towboat. The allision was a result of the pilot's becoming lost and disoriented in the dense fog, in part, the Board maintained, because of the U.S. Coast Guard's failure to establish higher standards for licensing operators of inland towing vessels. This interim rule arises largely from a cooperative effort between the Coast Guard and the towing industry.

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It has not been reviewed by the Office of Management and Budget under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040 (February 26, 1979)).

A Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT follows:

Benefits. The principal benefits of this rule will be to enhance the safety of navigation and to reduce the risk of collisions, allisions, groundings, and human casualties. We intend this rule to improve safety in the towing industry by increasing the levels of knowledge and proficiency of the mariners in charge of the navigation and safety of the towing vessel and crew. The training that is required by this rule should significantly decrease the number of fatalities and injuries in the towing industry and also reduce the amount of property damage.

We analyzed information from our Marine Safety Management System (MSMS) to quantify benefits. We concentrated our analysis of the benefits on data sets from 1996 through 1998. First, we analyzed all cases where death had occurred involving a towing vessel. There were 21 accidents resulting in 27 deaths. Secondly, we found about 1500 marine casualties involving towing vessels where a lack of knowledge or proficiency was cited as a causal factor. For the purpose of analysis we examined only the 50 cases where the total damage was the greatest.

Relying on narratives written by the Investigating Officers (IOs) of the Coast Guard, we assigned to cases probabilities depending on the likelihood that this rulemaking might have helped in preventing the casualty. We recognize that operator error is only one of the causal factors in many casualties. Consequently, we gave even incidents that earned a ''High'' probability (of avoidance through measures included in this rule) only a value of 20 to 40 percent. We gave those that earned a ''Low'' probability values of 5 to 15 percent.

We estimate that annual benefits from preventing deaths will range from $2,430,000 to $5,130,000, while annual benefits from preventing property damage will range from $1,158,987 to $2,546,694. The 10-year present value of total benefits should range from $25,207,543 to $53,917,886. The 10-year benefit-cost ratio of this rule should range from 2.59 to 5.54 with the average being 4.07.

Finally, this benefit analysis considered only a portion of the 1500 cases where a lack of knowledge or proficiency was cited as a causal factor. Also, we did not quantify any benefits from preventing injuries. Other areas where benefits exist, but were not quantified, were disruption of private automobile and commercial truck traffic when bridges are damaged, and environmental damage from spilled cargo.

Costs. There are around 5,400 documented towing vessels in the United States. This rule should have a minimal impact on the operators of these vessels because holders of current licenses will be grandfathered into new licenses commensurate with their experience. Because these new licenses will be issued at the time of routine renewal, there will be no new users' fees for them. The rule, however, will result in increased fees for new entrants into the towing industry.

Most revisions to the SNPRM, as reflected in this rule, either make editorial changes or update technical information to reflect comments to the SNPRM. But there are certain ones that are substantive and will require different actions by mariners. In response to comments from the public and TSAC, we now allow mariners who have not had administrative action taken against their license culminating in suspension or revocation to submit ''information'' and so forgo any demonstration of proficiency for license renewal.

We estimate the annual costs—including direct costs for new entrants into the industry and indirect costs associated with industry's increased paperwork burden—of compliance with this rule at $1,314,424. The 10-year present value of cost to industry, discounted at 7 percent back to 1998, would total $9,231,964.

The annual Federal Government costs include Coast Guard time and resources to review towing officers' assessment records for existing mariners, as well as the service records, applications, and check-ride results of entry mariners. We estimate the total costs the Government burden at $70,464 a year. The 10-year present value of government costs, discounted at 7 percent back to 1998, would total $494,910.

We estimate that the 10-year present value, discounted at 7 percent back to 1998, of costs to industry and Government would total $9,726,874.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

This rule will place its primary economic burden on the mariner, not on the mariner's employer. However, we will continue to require towing companies to maintain evidence that every vessel they operate is under the direction and control of a licensed mariner with appropriate experience, including 30 days of observation and training on the intended route (as currently required under 46 CFR part 15). These companies are also required under 46 CFR part 10 to record and document sea service of licensed personnel, which should satisfy the recordkeeping and documentation requirements for this rulemaking. This analysis considered all of the roughly 1,252 companies operating towing vessels to be small entities that will experience increased burdens. At an estimated increased burden of 2 hours a company per year, the total impact of this rule on small entities should be $42,568 a year (1,252 companies × 2 hours a company a year × $17 an hour). The estimated impact of 2 hours will not apply to all companies since many are already compiling the information required under this part. The estimated burden is a conservative estimate based upon current practice. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule will have a significant economic impact on it, please submit a comment to the Docket Management Facility at the address under **ADDRESSES.** In your comment, explain why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If this rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult Lieutenant Commander Luke Harden, Office of Operating and Environmental Standards (G–MSO), Coast Guard, telephone 202–267–0229; e-mail Lharden@comdt.uscg.mil. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). You may access the Small Business Administration's site on the Internet at http://www.sbaonline.sba.gov/SBDC/.

Collection of Information

This interim rule provides for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other, similar actions. The title and description of the collections, a description of the respondents, and an estimate of the total annual burden follow. The estimate accounts for the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

DOT No.: 2115.

OMB Control No.: 2115–0623

Title: Licensing and Manning for Officers of Towing Vessels.

Collection of Information: This interim rule requires every mariner who seeks either an original license as mate (pilot) of towing vessels or an endorsement for towing vessels to have a towing officers' assessment record. It also requires a report on a final check-ride before a designated examiner for every mariner seeking an original license.

Need for Information: The need for the collection of information is to ensure that the mariner's training information is available to assist in determining his or her overall qualification to hold a merchant mariner's license issued by the Coast Guard. These recordkeeping requirements are consistent with good commercial practices to the end of good seamanship for safe navigation. The following is a section-by-section explanation of them:

Section 10.304(h) requires each applicant for a license as mate (pilot) of towing vessels, and each master or mate of self-propelled vessels of greater than 200 gross tons seeking an endorsement for towing vessels, to complete a towing officers' assessment record.

Section 10.463(h) requires a company to maintain evidence that every vessel it operates is under the direction and control of a licensed mariner with appropriate experience, including 30 days of observation and training on the intended route. The company may do this with copies of current licenses and voyage records that most companies already keep.

Section 10.464(d)(2) requires masters of vessels of greater than 200 gross tons to maintain towing officers' assessment records for license endorsements as masters of towing vessels. Collection of this information is necessary to ensure that the masters have completed the series of qualification for the towing industry.

Sections 10.465(a)(2), (b)(2), (c)(2), and (d) each require a final check-ride before a designated examiner. Afterwards, they require the applicant to submit his or her completed towing officers' assessment record to the Coast Guard Regional Examination Center. Collection of this information is necessary because it will raise the safety of towing by upgrading the evaluation process.

Section 10.465(c) also requires mates of self-propelled vessels of greater than 200 gross tons to maintain towing officers' assessment records for license endorsements over new routes. Collection of this information is necessary to ensure that the mates have completed the series of qualification for the towing industry.

Proposed Use of Information: This information warrants the mariner qualified to hold a license for the service in which he or she would engage.

Description of Respondents: Mariners licensed to operate towing vessels, prospective towing-vessel officers, and companies employing these mariners.

Number of Respondents: 13,024 existing mariners of towing vessels, 320 new entrants to the industry, and about 1,252 companies employing these mariners.

Frequency of Response: Since licenses are valid for 5-year periods, the frequency of response for existing mariners should be 20 percent of existing mariners of towing vessels responding in any given year. Each year, all new applicants will have a paperwork burden.

The Coast Guard estimates that 95 percent of existing mariners will choose to maintain towing officers' assessment records as a method of renewal.

An estimated 1 percent of currently licensed mariners may complete a report on a final check-ride before a designated examiner every year. The estimated total percentage of currently licensed mariners who may complete a report on the final check-ride during a 5-year period is 5 percent. Final check-ride before a designated examiner under §§ 10.465(a)(2), (b)(2), and (c)(2) entails a one-time record after completion of the mariner's towing officers' assessment record.

About 1,252 companies must maintain files of licenses and voyage records for each mariner, to be revised upon the expansion of a mariner's route.

Burden of Response: About 95 percent of current licensed towing-vessel operators have to perform an estimated 1.0 hour of management time a year to provide the Coast Guard with updates of their licensing records. About 5 percent of these operators may have to perform an estimated 0.5 hour of management time over 5 years to provide the Coast Guard evidence of having performed the final check-ride. About 320 entry-level mariners seeking licenses to become such operators may have to perform an estimated 1.0 hour of management time apiece each year to provide the Coast Guard with updates of their licensing records.

Under § 10.463(h), about 1,252 companies will have to maintain evidence that every vessel they operate is under the direction and control of a licensed mariner with appropriate experience. (The total burden for each company should come to 2 hours for all of its mariners each year.)

The estimated cost to industry (companies and mariners) for this collection of information is $283,206 a year. The estimated cost to government is $70,464 a year.

Estimated Total Annual Burden: The total burden of reporting and recordkeeping for industry is 15,338 hours a year. The total burden of them for government is 2936 hours a year.

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted a copy of this rule to OMB for its review of the collection of information. We ask for public comment on the collection of information to help us determine how useful the information is; whether it can help us perform our functions better; whether it is readily available elsewhere; how accurate our estimate of the burden of collection is; how valid our methods for determining burden are; how we can improve the quality, usefulness, and clarity of the information; and how we can minimize the burden of collection.

If you submit comments on the collection of information, submit them both to OMB and to the Docket Management Facility where indicated under **ADDRESSES**, by the date under **DATES**.

You need not respond to a collection of information unless it displays a currently valid control number from OMB. Before the requirements for this collection of information become effective, we will publish notice in the **Federal Register** of OMB's decision to approve, modify, or disapprove the collection.

Federalism

We have analyzed this interim rule under E.O. 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This interim rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

We considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph (34)(c), of

Commandant Instruction M16475.lC, this rule is categorically excluded from further environmental documentation. This rule is a matter of ''training, qualifying, licensing, and disciplining of maritime personnel'' within the meaning of paragraph (34)(c) that clearly has no environmental impact. A ''Categorical Exclusion Determination'' is available in the docket where indicated under **ADDRESSES.**

List of Subjects

46 CFR Part 10

Reporting and recordkeeping requirements, Schools, Seamen.

46 CFR Part 15

Reporting and recordkeeping requirements, Seamen, Vessels.

For the reasons discussed in the preamble, the Coast Guard amends 46 CFR parts 10 and 15 as follows:

PART 10—LICENSING OF MARITIME PERSONNEL

1. Revise the authority citation for part 10 to read as follows:

Authority: 14 U.S.C. 633; 31 U.S.C. 9701; 46 U.S.C. 2101, 2103, and 2110; 46 U.S.C. Chapter 71; 46 U.S.C 7502, 7505, and 7701; 49 CFR 1.45 and 1.46. Section 10.107 is also issued under the authority of 44 U.S.C. 3507.

2. In § 10.103, revise the definition of *Inland waters*; and add the definitions of *Apprentice mate (steersman) of towing vessels, Approved training, Disabled vessel, Harbor assist,* and *Pilot of towing vessels,* in alphabetical order, to read as follows:

§ 10.103 Definitions of terms used in this part.

Apprentice mate (steersman) of towing vessels means a mariner qualified to perform watchkeeping on the bridge, aboard a towing vessel, while in training under the direct supervision of a licensed master or mate (pilot) of towing vessels.

* * * * *

Approved training means training that is approved by the Coast Guard or meets the requirements of § 10.309.

* * * * *

Disabled vessel means a vessel that needs assistance, whether docked, moored, anchored, aground, adrift, or under way; but does not mean a barge or any other vessel not regularly operated under its own power.

* * * * *

Harbor assist means the use of a towing vessel during maneuvers to dock, undock, moor, or unmoor a vessel, or to escort a vessel with limited maneuverability.

* * * * *

Inland waters means the navigable waters of the United States shoreward of the Boundary Lines as described in 46 CFR part 7, excluding the Great Lakes and Western Rivers. For establishing credit for sea service, the waters of the Inside Passage between Puget Sound and Cape Spencer, Alaska, are inland.

* * * * *

Pilot of towing vessels means a qualified officer of towing vessels operating only on inland routes.

* * * * *

§ 10.201 [Amended]

3. In § 10.201, in paragraph (f)(1), remove the words ''second-class operator of uninspected towing vessel'' and add, in their place, the words ''mate (pilot) of towing vessels''; and, in paragraph (f)(2), remove the words ''designated duty engineer of vessels of not more than 1,000 horsepower, may be granted to an applicant who has reached the age of 18 years'' and add, in their place, the words ''designated duty engineer of vessels of not more than 1,000 horsepower, or apprentice mate (steersman) of towing vessels, may be granted to an applicant, otherwise qualified, who has reached the age of 18 years''.

§ 10.203 [Amended]

4. In § 10.203, in Table 10.203, in column one, remove the word ''Uninspected'' from before the words ''towing vessels'' and capitalize the first letter in the word ''towing''; and, in column two, remove the words ''Operator: 21; 2/c operator: 19'' from the license category just amended to read ''Towing vessels'' and add, in their place, the words ''Master of towing vessels: 21; mate (pilot) of towing vessels: 19; apprentice mate (steersman): 18''.

§ 10.205 [Amended]

5. In § 10.205, in paragraph (f)(1), remove the words ''operator of uninspected towing vessels'' and add, in their place, the words ''master or mate (pilot) of towing vessels''; and revise paragraph (g)(3) to read as follows:

* * * * *

(g) * * *

(3) All licenses for master or mate (pilot), except apprentice mate (steersman), for towing vessels on oceans.

* * * * *

6. In § 10.209, add paragraphs (c)(6) and (7) to read as follows:

§ 10.209 Requirements for renewal of licenses, certificates of registry, and STCW certificates and endorsements.

* * * * *

(c) * * *

(6) Except as provided by paragraph (c)(7) of this section, an applicant for renewal of a license as master or mate (pilot) of towing vessels shall submit satisfactory evidence, predating the application by not more than 1 year, of satisfying the requirements of paragraph (c)(1)(i) or (ii) of this section, or those of paragraph (c)(1)(iv) of this section except the exercise; and of either—

(i) Completing a practical demonstration of maneuvering and handling a towing vessel before a designated examiner; or

(ii) Submitting documentation in the form of a towing officers' assessment record that lists training, drills, and experience during the license's validity in which an operator's proficiency is assessed over time.

(7) An applicant for renewal of a license as master or mate (pilot) of towing vessels whose most recent license was suspended or revoked by an administrative law judge for incompetence shall complete the practical demonstration rather than submit the towing officers' assessment record under paragraph (c)(6)(i) of this section.

* * * * *

7. In § 10.304, revise the section heading, redesignate paragraph (h) as (i), and add new paragraph (h) to read as follows:

§ 10.304 Substitution of training for required service, use of training-record books, and use of towing officer assessment records.

* * * * *

(h) Each applicant for a license as master or mate (pilot) of towing vessels, and each master or mate of self-propelled vessels of greater than 200 gross tons seeking an endorsement for towing vessels, shall complete a towing officers' assessment record that contains at least the following:

(1) Identification of the candidate, including full name, home address, photograph or photo-image, and personal signature.

(2) Objectives of the training and assessment.

(3) Tasks to perform or skills to demonstrate.

(4) Criteria to use in determining that the tasks or skills have been performed properly.

(5) A place for a qualified instructor to indicate by his or her initials that the candidate has received training in the proper performance of the tasks or skills.

(6) A place for a designated examiner to indicate by his or her initials that the candidate has successfully completed a practical demonstration and has proved competent in the task or skill under the criteria.

(7) Identification of each qualified instructor by full name, home address, employer, job title, ship name or business address, number of any Coast Guard license or document held, and personal signature.

(8) Identification of each designated examiner by full name, home address, employer, job title, ship name or business address, number of any Coast Guard license or document held, and personal signature confirming that his or her initials certify that he or she has witnessed the practical demonstration of a particular task or skill by the candidate.

* * * * *

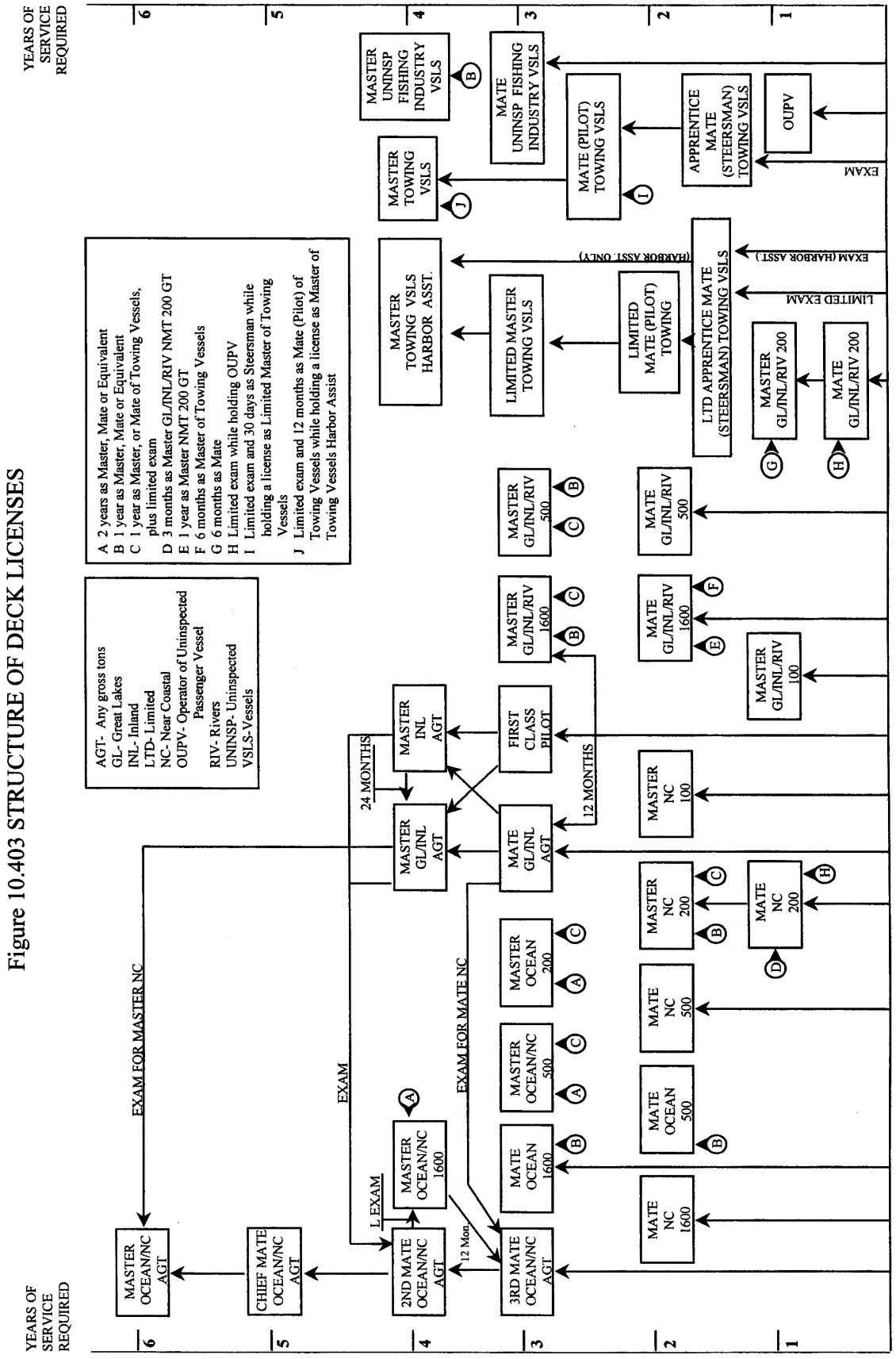
8. In § 10.403, revise the section heading and revise Figure 10.403 to read as follows:

§ 10.403 Structure of deck licenses.

* * * * *

BILLING CODE 4910–15–U

Figure 10.403 STRUCTURE OF DECK LICENSES



BILLING CODE 4910–15–C

§ 10.412 [Amended]

9. In § 10.412(a), remove the words ''operator of uninspected towing vessels,''.

§ 10.414 [Amended]

10. In § 10.414(a), remove the words ''operator of uninspected towing vessels,''.

11. Revise § 10.418(b) to read as follows:

§ 10.418 Service requirements for master of ocean or near-coastal steam or motor vessels of not more than 500 gross tons.

* * * * *

(b) The holder of a license as master or mate (pilot) of towing vessels authorizing service on oceans or near-coastal routes is eligible for a license as master of ocean or near-coastal steam or motor vessels of not more than 500 gross tons after both 1 year of service as master or mate of towing vessels on oceans or near-coastal routes and completion of a limited examination.

§ 10.420 [Amended]

12. In § 10.420, remove the words ''operator of uninspected towing vessels,''.

§ 10.424 [Amended]

13. In § 10.424(a)(2), remove the words ''operator or second-class operator of ocean or near-coastal uninspected towing vessels'' and add, in their place, the words ''master or mate of ocean or near-coastal towing vessels''.

14. Revise § 10.426(a)(2) to read as follows:

§ 10.426 Service requirements for master of near-coastal steam or motor vessels of not more than 200 gross tons.

(a) * * *

(2) One year of total service as licensed master or mate of towing vessels on oceans or near-coastal routes. Completion of a limited examination is also required.

* * * * *

§ 10.442 [Amended]

15. In § 10.442, paragraphs (a) and (b), remove the words ''operator of uninspected towing vessels'' from the two places where they occur and add, in their places, the words ''master of towing vessels''.

§ 10.444 [Amended]

15a. In § 10.444(c), remove the words ''second-class operator of uninspected towing vessels'' and add, in their place, the words ''mate (pilot) of towing vessels''.

§ 10.446 [Amended]

16. In § 10.446(b)—

a. In the first sentence, remove the word ''operator'' wherever it appears and add, in its place, the word ''master'' and remove the word ''uninspected'' wherever it appears; and

b. In the third sentence, remove the words ''operator or second-class operator of uninspected'' and add, in their place, the words '' master or mate (pilot) of''.

§ 10.452 [Amended]

17. In § 10.452(a), remove the words ''operator or second-class operator of uninspected towing vessels'' and add, in their place, the words ''master or mate (pilot) of towing vessels''.

§ 10.462 [Amended]

18. In § 10.462(c), remove the words ''operator of uninspected towing vessels'' and add, in their place, the words ''master or mate (pilot) of towing vessels''.

19. Add § 10.463 to read as follows:

§ 10.463 General requirements for licenses for master, mate (pilot), and apprentice mate (steersman) of towing vessels.

(a) The Coast Guard issues the following licenses:

(1) Master of towing vessels.

(2) Master of towing vessels, harbor assist.

(3) Master of towing vessels, limited.

(4) Mate (pilot) of towing vessels.

(5) Mate (pilot) of towing vessels, limited.

(6) Apprentice mate (steersman).

(7) Apprentice mate (steersman), harbor assist.

(8) Apprentice mate (steersman), limited.

(b) A master license means a license to operate a towing vessel not restricted to harbor assist and not restricted to a local area designated by the OCMI. This also applies to a mate (pilot) license.

(c) For this section, *limited* means a license to operate a towing vessel of less than 200 gross tons limited to a local area designated by the OCMI.

20. Revise § 10.464 to read as follows:

§ 10.464 Requirements for licenses as master of towing vessels.

(a) If you would like to obtain a license as master of towing vessels endorsed with a route listed in column 1 of Table 10.464–1, then you must complete the service requirements indicated in columns 2 through 5. If you would like to upgrade your license as master of towing vessels (harbor assist), then you must complete the service requirements listed in columns 6 through 9. You may serve on the subordinate routes listed in column 10 if you complete the observation and training required in column 11.

BILLING CODE 4910–15–U

BILLING CODE 4910-15-C

TABLE 10.464-1--REQUIREMENTS FOR LICENSE AS MASTER OF TOWING VESSELS

1 ROUTE ENDORSED	2 TOTAL SERVICE[1]	3 TOS[2] ON T/V AS MATE (PILOT)	4 TOS[2] ON T/V AS MATE (PILOT) NOT AS HARBOR ASSIST	5 TOS[2] ON PARTICULAR ROUTE	6 TOS[2] AS MATE (PILOT) WHILE HOLDING MASTER (HARBOR ASSIST)	7 TOS[2] ON PARTICULAR ROUTE	8 TOAR[5]	9 PASSED APPROPRIATE ROUTE EXAMINATION[3]	10 SUB-ORDINATE ROUTE AUTHORIZED	11 DAYS OF OBSERVATION AND TRAINING REQUIRED[4]
(1) OCEANS (O)	48	18 of 48	12 of 18	3 of 18	12	3 of 12	YES	YES	NC, GL-I, R WR LLA	30 90 30
(2) NEAR-COASTAL (NC)	48	18 of 48	12 of 18	3 of 18	12	3 of 12	YES	YES	GL-I, R WR LLA	30 90 30
(3) GREAT LAKES-INLAND (GL-I)	48	18 of 48	12 of 18	3 of 18	12	3 of 12	YES	YES	R WR LLA	30 90 30
(4) RIVERS (R)	48	18 of 48	12 of 18	3 of 18	12	3 of 12	YES	YES	WR LLA	90
(5) WESTERN RIVERS (WR)	48	18 of 48	12 of 18	3 of 18	12	3 of 12	YES	YES	LLA	30 30

1 Service is in months.

2 TOS is time of service.

3 The COTP determines the appropriate route examination for the desired endorsement.

4 If you hold a license as master of towing vessels you may have a restricted endorsement, as mate (pilot) for a route not included in the current endorsements on which you have no operating experience, placed on your license after passing an examination for that route. Upon completion of 90 days of experience on that route, you may have the endorsement removed. This is instead of the requirement listed in this column.

5 TOAR is training officers' assessment record.

(b) If you would like to obtain a license as master of towing vessels (harbor assist) endorsed with a route listed in column 1 of Table 10.464–2, then you must complete the service requirements indicated in columns 2 through 5. If you would like to upgrade your license as master of towing vessels (limited), then you must complete the service requirements listed in columns 6 and 7, and either 8, 9, or 10. You may serve on the subordinate routes listed in column 11 if you complete the observation and training required in column 12.

BILLING CODE 4910–15–U

TABLE 10.464-2--REQUIREMENTS FOR LICENSE AS MASTER OF TOWING VESSELS (HARBOR ASSIST)

1 ROUTE ENDORSED	2 TOTAL SERVICE[1]	3 TOS[2] ON T/V AS APPREN-TICE MATE	4 TOS[2] ON T/V AS APPREN-TICE MATE CONDUCT-ING HARBOR ASSIST	5 TOS[2] ON PARTICULAR ROUTE	6 TOS[2] ON T/V CONDUCTING HARBOR ASSIST WHILE LICENSED AS MASTER (LIMITED)	7 TOS[2] ON PARTICULAR ROUTE	8 COURSE	9 TOAR[3]	10 30 DAYS OF OBSERVATION AND TRAINING AND PASSED A LIMITED EXAMINATION	11 SUB-ORDINATE ROUTE AUTH'D	12 DAYS OF OBSER-VATION AND TRAINING REQ'D
(1) GREAT LAKES-INLAND (GL-I)	48	30 of 48	18 of 30	18 of 30	12	3 of 12	YES	YES	YES	R WR LLA	30 90 30
(2) RIVERS (R)	48	30 of 48	18 of 30	18 of 30	12	3 of 12	YES	YES	YES	WR LLA	90 30
(3) WESTERN RIVERS (WR)	48	30 of 48	18 of 30	18 of 30	12	3 of 12	YES	YES	YES	LLA	30
(4) LIMITED LOCAL AREA (LLA)	48	30 or 48	18 of 30	18 of 30	12	3 of 12	YES	YES	YES		

1 Service is in months.
2 TOS is time of service.
3 TOAR is training officers' assessment record.

(c) If you would like to obtain a license as master of towing vessels (limited), then you must complete the service requirements listed in Table 10.464–3.

TABLE 10.464–3.—REQUIREMENTS FOR LICENSE AS MASTER OF TOWING VESSELS (LIMITED)

1 Route endorsement	2 Total service [1]	3 TOS [2] on T/V as limited mate (pilot)	4 TOS [2] on particular route
LIMITED LOCAL AREA (LLA)	36	12 of 36	3 of 12.

[1] Service is in months.
[2] TOS is time of service.

(d) The Coast Guard restricts licenses as master of towing vessels for oceans and near-coastal routes by the gross tonnage of the towing vessels on which the experience was acquired by 200, 500, 1,600 gross tons, per §§ 10.424, 10.418, and 10.412 of this part, respectively.

(e) Before you serve as master of towing vessels on the Western rivers, you must possess 90 days of observation and training and have your license endorsed for Western Rivers.

(f) Each company must maintain evidence that every vessel it operates is under the direction and control of a licensed mariner with appropriate experience, including 30 days of observation and training on the intended route other than Western Rivers.

(g) If you hold a license as master of self-propelled vessels of greater than 200 gross tons and first-class pilot then you may obtain an endorsement for towing vessels (restricted to the service presented) if you—

(1) Have 30 days of training and observation on towing vessels on each of the routes for which the endorsement is sought, except as noted in paragraph (e) of this section;

(2) Submit a towing officers' assessment record described in § 10.304(h) that exhibits evidence of assessment of practical demonstration of skills; and

(3) Pass an examination.

21. Add § 10.465 to read as follows:

§ 10.465 Requirements for licenses as mate (pilot) of towing vessels.

(a) If you would like to obtain a license as mate (pilot) of towing vessels endorsed with a route listed in column 1 of Table 10.465–1, then you must complete the service requirements indicated in columns 2 through 4 and either 5 or 6. If you hold a license as master of towing vessels (harbor assist or limited) and would like to upgrade it to mate (pilot), then you must complete the requirements in column 7. If you hold a license as mate (pilot)(limited) and would like to upgrade it to mate (pilot), then you must complete the requirements in columns 2 through 6 and pass a limited examination. You may serve on the subordinate routes listed in column 8 if you complete the observation and training required in column 9.

BILLING CODE 4910-15-C

TABLE 10.465-1--REQUIREMENTS FOR LICENSE AS MATE (PILOT[5]) OF TOWING VESSELS

1 ROUTE ENDORSED	2 TOTAL SERVICE [1]	3 TOS[2] ON T/V AS APPRENTICE MATE (STEERSMAN)	4 TOS[2] ON PARTICULAR ROUTE	5 COURSE	6 TOAR[3]	7 30 DAYS OF OBSERVATION AND TRAINING WHILE HOLDING MASTER (HARBOR ASSIST OR LIMITED) AND PASS A LIMITED EXAMINATION	8 SUBORDINATE ROUTE AUTHORIZED	9 DAYS OF OBSERVATION AND TRAINING REQUIRED[4]
(1) OCEANS (O)	30	12 of 30	3 of 12	YES	YES	YES	NC, GL-I, R WR LLA	30 90 30
(2) NEAR-COASTAL (NC)	30	12 of 30	3 of 12	YES	YES	YES	GL-I, R WR LLA	30 90 30
(3) GREAT LAKES-INLAND (GL-I)	30	12 of 30	3 of 12	YES	YES	YES	R WR LLA	30 90 30
(4) RIVERS (R)	30	12 of 30	3 of 12	YES	YES	YES	WR LLA	90 30
(5) WESTERN RIVERS (WR)	30	12 of 30	3 of 12	YES	YES	YES	LLA	30

1 Service is in months.

2 TOS is time of service.

3 TOAR is training officers' assessment record.

4 If you hold a license as mate (pilot) of towing vessels you may obtain a restricted endorsement as apprentice mate (steersman). This endorsement will go on your license after you pass an examination for a route that is not included in the current endorsements and on which you have no operating experience. Upon completion of 3 months of experience on that route, you may have the restricted endorsement removed. This is instead of the requirement listed in this column.

5 For all inland routes, as well as Western Rivers, the license as pilot of towing vessels is equivalent to that as mate of towing vessels. All qualifications and equivalencies are the same.

(b) The Coast Guard restricts licenses as mate (pilot) of towing vessels for oceans and near-coastal routes by the gross tonnage of the towing vessels on which the experience was acquired-by 200, 500, 1,600 gross tons, under §§ 10.424, 10.418, and 10.412 of this part, respectively.

(c) Before you serve as mate (pilot) of towing vessels on the Western Rivers, you must possess 90 days of observation and training and have your license endorsed for Western Rivers.

(d) Each company must maintain evidence that every vessel it operates is under the direction and control of a licensed mariner with appropriate experience, including 30 days of observation and training on the intended route other than Western Rivers.

(e) If you would like to obtain a license as mate (pilot) of towing vessels (limited), then you must complete the service requirements listed in Table 10.465–2.

TABLE 10.465–2.—REQUIREMENTS FOR LICENSE AS MATE (PILOT) OF TOWING VESSELS (LIMITED)

1 Route endorsement	2 Total service [1]	3 TOS [2] on T/V as apprentice mate (steerman)	4 Certificate of course completion—training officers' assessment record
LIMITED LOCAL AREA (LLA)	24	6 of 24	Either.

[1] Service is in months.
[2] TOS is time of service.

(f) If you hold a license as mate of self-propelled vessels of greater than 200 gross tons and one as first-class pilot then you may obtain an endorsement for towing vessels (restricted to the service presented) if you—

(1) Have 30 days of training and observation on towing vessels on each of the routes for which you seek the endorsement, except as noted in paragraph (c) of this section;

(2) Submit a towing officers' assessment record described in § 10.304(h) that exhibits evidence of assessment of practical demonstration of skills; and

(3) Pass an examination.

(g) An approved training course for mate (pilot) of towing vessels must include formal instruction and practical demonstration of proficiency either on board a towing vessel or at a shoreside training facility before a designated examiner, and must cover—

(1) Shipboard management and training;
(2) Seamanship;
(3) Navigation;
(4) Watchkeeping;
(5) Radar;
(6) Meteorology;
(7) Maneuvering and handling of towing vessels;
(8) Engine-room basics; and
(9) Emergency procedures.

§ 10.466 Redesignated as § 10.467

22. Redesignate § 10.466 as § 10.467 and add a new § 10.466 to read as follows:

§ 10.466 Requirements for licenses as apprentice mate (steersman) of towing vessels.

(a) If you would like to obtain a license as apprentice mate (steersman) of towing vessels listed in column 1 endorsed with a route listed in column 2 of Table 10.466–1, then you must complete the service requirements indicated in columns 3 through 6.

TABLE 10.466–1.—REQUIREMENTS FOR LICENSE AS APPRENTICE MATE (STEERSMAN [4]) OF TOWING VESSELS

1 License type	2 Route endorsed	3 Total service [1]	4 TOS [2] on T/V	5 TOS [2] on particular route	6 Pass examination [3]
(1) APPRENTICE MATE (STEERSMAN).	OCEANS (O)	18	12 of 18	3 of 18	Yes.
	NEAR-COASTAL (NC)	18	12 of 18	3 of 18	Yes.
	GREAT LAKES-INLAND (GL–I)	18	12 of 18	3 of 18	Yes.
	RIVERS (R)	18	12 of 18	3 of 18	Yes.
	WESTERN RIVERS (WR)	18	12 of 18	3 of 18	Yes.
(2) APPRENTICE MATE (STEERSMAN) (HARBOR ASSIST).	NOT APPLICABLE	18	12 of 18	3 of 18	Yes.
(3) APPRENTICE MATE (STEERSMAN) (LIMITED) [4].	NOT APPLICABLE	18	12 of 18	3 of 18	Yes.

[1] Service is in months.
[2] TOS is time of service.
[3] The examination for apprentice mate is specified in subpart I of this part. The examination for apprentice mate (limited) is a limited examination.
[4] For all inland routes, as well as Western Rivers, the license as steersman is equivalent to that as apprentice mate. All qualifications and equivalencies are the same.

(b) If you hold a license as apprentice mate (steersman) of towing vessels you may obtain a restricted endorsement as limited apprentice mate (steersman). This endorsement will go on your license after you pass an examination for a route that is not included in the current endorsements and on which you have no operating experience. Upon completion of 3 months of experience on that route, you may have the restricted endorsement removed.

23. Revise § 10.482(a) to read as follows:

§ 10.482 Assistance towing.

(a) This section contains the requirements to qualify for an endorsement authorizing an applicant to engage in assistance towing. The endorsement applies to all licenses except those for master and mate (pilot) of towing vessels and those for master or mate authorizing service on inspected vessels over 200 gross tons. Holders of any of these licenses may engage in assistance towing within the scope of the licenses and without the endorsement.

* * * * *

§ 10.701 [Amended]

24. In § 10.701(a), remove the words ''operator of uninspected towing vessels'' and add, in their place, the words ''master or mate (pilot) of towing vessels''.

§ 10.703 [Amended]

25. In § 10.703(a), remove the words ''operator of uninspected towing vessels'' and add, in their place, the words ''master or mate (pilot) of towing vessels''.

§ 10.901 [Amended]

26. In § 10.901(b)(1), remove the words ''uninspected towing vessels'' and add, in their place, the words ''master or mate (pilot) of towing vessels''.

27. In § 10.903—

a. In paragraph (c) in Table 10.903–1, in the entry for STCW CODE II/2, p. 3 & 4, add an ''X'' in column 7;

b. In paragraph (c) in Table 10.903–1, in the entry for STCW CODE II/3, remove the ''X'' in column 7; and

c. Revise paragraphs (a)(18), (b)(4), and (c)(7) to read as follows:

§ 10.903 Licenses requiring examinations.

(a) * * *

(18)(i) Apprentice mate (steersman) of towing vessels;

(ii) Apprentice mate (steersman) of towing vessels, harbor assist;

* * * * *

(b) * * *

(4) Master or mate (pilot) of towing vessels (endorsed for the same route).

(c) * * *

(7) Master or mate of towing vessels of over 200 gross tons, oceans (domestic trade) and near-coastal.

* * * * *

28. In § 10.910, revise paragraphs 10 through 12 in Table 10.910–1 to read as follows:

§ 10.910 Subjects for deck licenses.

* * * * *

10. Apprentice mate, towing vessels, ocean (domestic trade) and near-coastal routes.

11. Apprentice mate (steersman), towing vessels, Great Lakes and inland routes.

12. Steersman, towing vessels, Western Rivers.

* * * * *

PART 15—MANNING REQUIREMENTS

29. Revise the authority citation for part 15 to read as follows:

Authority: 46 U.S.C. 2101, 2103, 3306, 3703, 8101, 8102, 8104, 8105, 8301, 8304, 8502, 8503, 8701, 8702, 8901, 8902, 8903, 8904, 8905(b), and 9102; and 49 CFR 1.45 and 1.46.

§ 15.301 [Amended]

30. Section 15.301 is amended as follows:

a. In paragraph (a), add the definition of *Disabled Vessel*, in alphabetical order;

b. Remove paragraph (b)(6); and

c. Redesignate paragraphs (b)(7) through (10) as paragraphs (b)(6) through (9).

The addition to § 15.301(a) reads as follows:

(a) * * *

Disabled vessel means a vessel that needs assistance, whether docked, moored, anchored, aground, adrift, or under way; but does not mean a barge or any other vessel not regularly operated under its own power.

* * * * *

31. Revise § 15.610 to read as follows:

§ 15.610 Master and mate (pilot) of towing vessels.

Every towing vessel at least 8 meters (at least 26 feet) in length measured from end to end over the deck (excluding sheer), except a vessel described by the next sentence, must be under the direction and control of a person licensed as master or mate (pilot) of towing vessels or as master or mate of vessels of appropriate gross tonnage holding an endorsement on his or her license for towing vessels. This does not apply to any vessel engaged in assistance towing, or to any towing vessel of less than 200 gross tons engaged in the offshore mineral and oil industry if the vessel has sites or equipment of that industry as its place of departure or ultimate destination.

§ 15.705 [Amended]

32. In § 15.705(d), remove the words ''individual operating an uninspected towing vessel'' and add, in their place, the words ''master or mate (pilot) operating a towing vessel''; and remove the words ''individuals serving as operators of uninspected towing vessels'' and add, in their place, the words ''masters or mates (pilots) serving as operators of towing vessels''.

33. In § 15.805, add paragraph (a)(5) to read as follows:

§ 15.805 Master.

(a) * * *

(5) Every towing vessel of at least 8 meters (at least 26 feet) or more in length.

* * * * *

34. In § 15.810, redesignate paragraphs (d) and (e) as (e) and (f); and add a new paragraph (d) to read as follows:

§ 15.810 Mates.

* * * * *

(d) Each person in charge of the navigation or maneuvering of a towing vessel of at least 8 meters (at least 26 feet) in length shall hold either a license authorizing service as mate of towing vessels—or, on inland routes, as pilot of towing vessels—or a license as master of vessels of appropriate gross tonnage according to the routes, endorsed for towing vessels.

* * * * *

35. Revise § 15.910 to read as follows:

§ 15.910 Towing vessels.

No person may serve as master or mate (pilot) of any towing vessel of at least 8 meters (at least 26 feet) in length unless he or she holds a license authorizing such service.

Dated: November 9, 1999.

R.C. North,

Rear Admiral, U.S. Coast Guard Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 99–29832 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–15–U

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 6 and 7

[WT Docket 96–198; FCC 99–181]

Access to Telecommunications Service, Telecommunications Equipment and Customer Premises Equipment by Persons with Disabilities

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document establishes rules to ensure that people with disabilities have access to telecommunications services and related equipment, if readily achievable. These rules are required to implement section 255 of Telecommunications Act

of 1996. These rules will increase the accessible products and services available in the marketplace.

DATES: These rules become effective January 28, 2000, except for §§ 6.18 and 7.18, which contain modified information collection requirements that have not been approved by the Office of Management and Budget (''OMB''). The Commission will publish a document in the **Federal Register** announcing the effective date of those sections. Written comments by the public on the modified information collection requirements should be submitted on or before December 20, 1999.

ADDRESSES: Office of the Secretary, Federal Communications Commission, 445 Twelfth Street SW, Room TW–A325, Washington, DC 20554. A copy of any comments on the information collection contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 1C804, 445 12th Street, SW, Washington, DC 20554, or via the internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Ellen Blackler, Common Carrier Bureau. (202) 418–0491.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order in WT Docket 96–198, adopted on July 14, 1999 and released on September 29, 1999. The full text of the Report and Order, including Commissioners' statements, is available for inspection and copying during normal business hours in the FCC Reference Center, 445 Twelfth Street, SW, Room CY–257, Washington, D.C. Alternate formats (computer diskette, large print, audio cassette and Braille) are available to persons with disabilities by contacting Martha Contee at (202) 418–0260 (voice), (202) 418–2555 (TTY), or at mcontee@fcc.gov. The Report and Order can be downloaded in WP or ASCII text at: http//www.fcc.gov/dtf/.

This report and order contains modified information subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under Section 3507(d) of the PRA. OMB, the general public and other federal agencies are invited to comment on the modified information collection contained in this proceeding.

Synopsis of Report and Order

1. In this Report and Order (Order) we adopt rules and policies to implement sections 255 and 251(a)(2) of the Communications Act of 1934, as amended (Act). These provisions, which were added by the Telecommunications Act of 1996 (1996 Act), are the most significant opportunity for the advancement of people with disabilities since the passage of the Americans with Disabilities Act (ADA) in 1990. These rules are based on the Access Boards Guidelines, 63 FR 5631, and the comments after issuance of a Notice of Proposed Rulemaking, 63 FR 28456.

2. We conclude that we have authority to adopt regulations to implement section 255. We find that the language of section 255(f), which bars any private right of action ''to enforce any requirement of this section or *any regulation thereunder*,'' expressly contemplates the Commission's enactment of regulations to carry out its enforcement obligations under the provisions of section 255. We conclude that at a minimum, section 255 itself grants us authority to enact rules to implement the provisions of section 255.

3. The extensive record herein supports the adoption of rules consistent with the Access Board's guidelines. Accordingly, we adopt rules in this Order that are identical to or based upon the Access Board guidelines, with a few minor exceptions. We conclude that the Access Board guidelines can effectively serve as the basis of rules for both covered services and equipment.

4. We note, however, that we have the discretion to depart from the Access Board guidelines where merited. We find that the Commission would not be bound to adopt the Access Board's guidelines as its own, or to use them as minimum standards, if it were to conclude, after notice and comment, that such guidelines were inappropriate.

I. Requirements for Covered Entities

5. As stated in the statute, a manufacturer of telecommunications equipment or customer premises equipment shall ensure that the equipment is designed, developed, and fabricated to be accessible to and usable by individuals with disabilities, if readily achievable. Second, a provider of telecommunications service shall ensure that the service is accessible to and usable by individuals with disabilities, if readily achievable. Finally, whenever the requirements set forth above are not readily achievable, such a manufacturer or provider shall ensure that the equipment or service is compatible with existing peripheral devices or specialized customer premises equipment commonly used by individuals with disabilities to achieve access, if readily achievable.

6. We adopt the ADA definition of disability in its entirety, as required under section 255 of the Act. We further agree with commenters that, in implementing section 255, we should follow any applicable judicial and administrative precedent stemming from this definition, except in those limited circumstances in which such precedent is shown to be unsuitable to a specific factual situation.

7. We conclude further that, at a minimum, the statutory reference to ''individuals with disabilities'' includes those with hearing, vision, movement, manipulative, speech, and cognitive disabilities. By no means, however, is the definition of ''disability'' limited to these specific groups. Determinations of what constitutes a ''disability'' under section 255 must be made on a case-by-case basis.

8. We adopt the Access Board's definitions of ''accessible to'' and ''usable by.'' We initially proposed in the *NPRM* to combine these terms under one definition under our rules, reasoning that the term ''accessible to'' should be used in its broadest sense to refer to the ability of persons with disabilities actually to use the equipment or service by virtue of its inherent capabilities and functions. Upon further review, however, we believe that it is more precise, and will provide clearer guidance to entities covered by section 255, for us to follow the lead of the Access Board and define these two terms separately because the requirements of ''accessible to'' and ''usable by'' embrace two distinct concepts. Although the Access Board guidelines were designed in the context of equipment and CPE accessibility, we conclude that these guidelines are equally applicable to the services context, and thus our definition of accessibility and usable applies to both equipment and services. We also adopt the proposal made in the NPRM to ensure that support services (such as consumer information and documentation) associated with equipment and services are accessible to and usable by people with disabilities.

9. We conclude that, with one technical exception and one addition, the input, control and mechanical functions in § 1193.41 of the Access Board guidelines and the output, display and control functions in § 1193.43 of the Access Board guidelines shall constitute the definition of ''accessible to'' under the Commission's rules. The list is not a set of mandates, but rather a list of areas covered entities should be considering when designing products and services.

10. We do not adopt § 1193.43(e) of the Access Board rules, which would require that volume control telephones provide a minimum of 20 dB adjustable volume gain. We decline to adopt this 20 dB volume control standard under our rules because it conflicts with rules that we have previously adopted pursuant to the Hearing Aid Compatibility Act.

11. We also do not adopt a separate requirement regarding net reductions similar to that in section 1193.30 of the Access Board's guidelines. We believe that this requirement is addressed under the readily achievable definition and analysis. The flexibility of the readily achievable analysis recognizes that it will generally be unacceptable to completely eliminate an existing accessibility feature, but that legitimate feature trade-offs as products evolve are not prohibited.

12. We do, however, add to our rules one input factor to the list developed by the Access Board. Specifically, the definition of ''accessible to'' shall include being ''operable with prosthetic devices.'' Because some people with disabilities rely on prosthetic devices, we conclude that consideration of direct access by such persons is appropriately encompassed in the definition of ''accessible to''.

13. We adopt the Access Board's definition of ''usable by'' as our definition under the rules. As many commenters that addressed this issue recognized, providing access to all supporting documentation and support services is an essential ingredient for the successful implementation of section 255 and is encompassed by our definition of ''usable by.'' Support services include, but are not limited to, access to technical support hotlines and databases, access to repair services, billing and any other services offered by a manufacturer or service provider that facilitate the continued and complete use of a product or service. Support services also include efforts by manufacturers and service providers to educate its sales force about the accessibility of their products and how accessibility features can be used.

14. We further conclude, consistent with the Access Board's guidelines and supported by the record, that ''usable by'' means manufacturers and service providers ensure that consumers with disabilities are included in product research projects, focus groups, and product trials, where applicable, to further enhance the accessibility and usability of a product, if readily achievable.

15. We also conclude, consistent with the Access Board guidelines and the statutory definition of CPE, that specialized CPE, such as direct-connect TTYs, are considered a subset of CPE. The statute's requirement that manufacturers and service providers ensure compatibility with CPE which has a specialized use does not change the fact that this equipment still meets the definition of CPE as discussed *infra* in paragraphs 80 *et. seq.* We define specialized CPE as CPE which is commonly used by individuals with disabilities to achieve access. Thus, manufacturers and service providers have the same obligations to ensure accessibility and usability of SCPE as they do for any other CPE.

16. We adopt four of the five criteria set forth by the Access Board as the definition of ''compatibility'' under section 255. We do not adopt the criterion of ''compatibility of controls with prosthetic devices,'' which we have instead added to the definition of accessibility. We adopt the Access Board's definitions of ''peripheral devices'' and ''specialized CPE.'' As proposed in the *NPRM*, the definitions of the terms ''peripheral devices'' and ''specialized CPE'' limit the compatibility requirement to those devices that have a specific telecommunications function or are designed to be used primarily to achieve access to telecommunications.

17. A manufacturer or service provider must assess whether it is readily achievable to install features or design equipment and services so that the equipment or service can meet the criteria of compatibility. Compliance with these criteria must be mandatory. As technology evolves, the guidelines and the definition of ''compatibility'' may need to be revised.

18. We require manufacturers and service providers to exercise due diligence to identify the types of peripheral devices and specialized CPE ''commonly used'' by people with disabilities with which their products and services should be made compatible, if it has not been readily achievable to make those products and services accessible. In the *NPRM*, we had proposed using the concepts of affordability and availability to help define the statutory term ''commonly used'' in section 255(d) of the Act. We conclude that affordability and general market availability are insufficient, and in some cases inappropriate, criteria for determining whether a specific peripheral device or piece of specialized CPE is ''commonly used'' by persons with disabilities.

19. Section 251(a)(2) of the Act requires that telecommunications carriers not install network features, functions, or capabilities that do not comply with the guidelines or standards established pursuant to section 255. We conclude that telecommunications carriers must not install service logic and databases associated with routing telecommunications services, whether residing in hardware or software, that do not comply with the accessibility requirements of these rules.

II. Readily Achievable

1. Definition of ''Readily Achievable''

20. We adopt the ADA's definition of ''readily achievable.'' We agree with the DOJ that this definition is intended to ensure that a ''wide range of factors be considered in determining whether an action is readily achievable.''

21. The primary focus of a ''readily achievable'' analysis should be upon three general considerations delineated in the ADA definition, namely (1) the cost of the action; (2) the nature of the action; and (3) the overall resources available to the entity, including resources made available to the entity by a parent corporation, if applicable, depending on the type of operation and the relationship between the two entities. We decline to include consideration of feasibility, expense, and practicality, as proposed in our *NPRM*. We have modified the definition so that it more closely correlates with the terms used in section 255. For example, we have replaced the word ''facility'' throughout the definition with the terms ''manufacturer'' and ''service provider,'' as appropriate. We also have inserted the terms ''if applicable'' before the third and fourth prongs of the definition. Furthermore, we agree with those parties who have argued that, in interpreting section 255, we should look to the ''substantial body of judicial decisions interpreting and applying'' the terms of the ADA, including the phrase ''readily achievable.''

2. Application of Readily Achievable

a. In General

22. In implementing the requirements of section 255, we decline to adopt a ''product line'' framework proposed primarily by manufacturers of equipment. Under this approach, a manufacturer or service provider would not need to conduct a ''readily achievable'' analysis for each produce or service, but instead would ensure that select products within its product lines are accessible to persons with disabilities. We conclude that section 255, by its terms, applies to the design and production of individual products and service offered by a manufacturer or service provider.

23. We recognize that there are accessibility features that can be incorporated into the design of products with very little or no difficulty or expense. These features must be deployed universally. We will not identify specific features that fall into this category, because it necessarily varies given the individual circumstances. Manufacturers and service providers must make their own determinations based on the factors in the readily achievable definition. Thus, manufacturers and service providers cannot decline to incorporate modest features that will enhance accessibility simply because some other product or service with the feature may be available. We expect that, over time, more and more features will be incorporated into all products in this manner, and that features that today may not be readily achievable soon will become routine and universally adopted.

24. With respect to those features or actions that are not readily achievable to be deployed universally, but are readily achievable to be incorporated into some products and services, manufacturers and service providers have the flexibility to distribute those features across product or service lines as long as they do all that is readily achievable. In addition, we expressly encourage manufacturers and service providers to work closely with the disability community to ensure that under-represented disability groups, and multiple disabilities (such as deaf-blindness), are not ignored.

25. In those instances where accessibility under paragraphs (b) or (c) of section 255 is not readily achievable, service providers and manufacturers are required to comply with paragraph (d), which states that they must ensure that their equipment or services are compatible with existing specialized CPE or peripheral devices commonly used by persons with disabilities to achieve access, if readily achievable.

26. We believe this framework will provide manufacturers and service providers a viable means for compliance with section 255, while promoting accessibility to the maximum extent possible. We expect that different companies, faced with their unique circumstances, may well come to different conclusions about deployment of accessibility features. We believe that is a desirable outcome that will maximize the range and depth of accessible products and services available to customers and will capitalize on the positive forces of competition.

b. Cost of the Action Needed

27. We conclude that ''cost,'' for purposes of the ''readily achievable'' evaluation, is the incremental amount that a manufacturer or service provider expends to design, develop, or fabricate a product or service to ensure that it is accessible. Although we tentatively concluded in the *NPRM* that it would be appropriate to consider net costs, taking into account such factors as the potential for recovery of expenses from consumers through increased sales or higher product prices, we now reject that approach for several reasons. We believe that an assessment of market factors, such as the ability of a service provider or manufacturer to recover its costs through price changes, would involve speculation. Moreover, not considering market factors is consistent with ADA precedent, and we are not convinced that there are any factors specific to telecommunications that compel us to adopt an interpretation of costs different from that under the ADA. We also are persuaded that introducing cost recovery or market considerations into the meaning of ''cost'' could defeat one of the primary purposes of section 255—enhancing access to telecommunications equipment and service for a population whose needs have not been addressed by the market alone.

28. While we have concluded that we will not consider market factors in determining what is readily achievable, we do not rule out the ability of manufacturers and service providers to take these market factors into account when making the decisions regarding deployment of more significant readily achievable accessibility features throughout its products.

29. We will permit manufacturers and service providers to consider the cost of disability access actions for a product or service in conjunction with the cost of other actions taken by them to comply with these rules during a fiscal period, as proposed by a number of commenters. We agree it may be appropriate to consider the cost of other accessibility actions as a factor in determining whether a measure is readily achievable. Therefore, manufacturers and service providers may take into account the cumulative cost of all accessibility actions over a specific fiscal period in determining whether an action is ''readily achievable.'' We underscore, however, that ''cumulative costs'' cannot be the only factor used by a manufacturer or service provider to determine whether a measure is ''readily achievable.'' In particular, the ability to take into account cumulative costs shall not permit a manufacturer or service provider to predetermine caps or quotas on its total spending for section 255 compliance for a given fiscal period.

30. A manufacturer or service provider may consider whether inclusion of an accessibility feature significantly will delay production or release of a product, and therefore increase production costs, provided that the manufacturer or service provider demonstrates that it did in fact consider accessibility at the design stage. Of course, the mere fact that inclusion of a feature will add time and cost to production will not, alone, render the measure not readily achievable.

c. Nature of the Action Needed

31. Another consideration in the ''readily achievable'' analysis is the nature of the action needed to make equipment or service accessible to persons with disabilities. While commenters generally have not framed their comments in terms of ''nature of the action,'' many address the concepts of ''fundamental alterations'' and ''technical feasibility,'' which we believe fall within the ambit of ''nature of the action.''

32. We agree with the Access Board found that the ''fundamental alteration'' concept derives from the ''undue burden'' test under the ADA and, since ''undue burden'' is a higher standard than ''readily achievable,'' that the concept of fundamental alteration is implicit in the readily achievable analysis. Since a covered entity must, hypothetically, demonstrate a much more onerous burden in order to be relieved of any obligations under the ''undue burden'' standard of the ADA, it follows that any actions that constitute an undue burden, including fundamental alterations, are also not ''readily achievable.'' Manufacturer or service provider is not required to install an accessibility feature if it can demonstrate that the feature fundamentally would alter the product.

33. In the *NPRM*, we tentatively concluded that technical infeasibility should be one factor in determining whether an accessibility feature is readily achievable. We now conclude that, when assessing the ''nature of the action'' in a readily achievable analysis, manufacturers and service providers are not required to incorporate accessibility features that are technically infeasible, subject to several limitations.

34. We agree with several commenters, however, that in some rare instances, ''technical infeasibility'' may result from legal or regulatory constraints. We also agree with several

commenters that technical infeasibility encompasses not only a product's technological limitations, but also its physical limitations. We note, however, that manufacturers and service providers should not make conclusions about technical infeasibility within the ''four corners'' of a product's current design. Section 255 requires a manufacturer or service provider to consider physical modifications or alterations to the existing design of a product. Finally, we agree with commenters that manufacturers and service providers cannot make bald assertions of technical infeasibility. Any engineering or legal conclusions that implementation of a feature is technically infeasible should be substantiated by empirical evidence or documentation.

d. Resources of the Covered Entity

35. We conclude that we should follow the two-step analysis of a covered entity's resources set forth by the DOJ in its ADA regulation. Accordingly, the resources of the ''covered entity'' (i.e., the manufacturer or service provider) first are examined. The resources of any parent corporation or comparable entity with a legal relationship with the manufacturer or service provider would be examined and taken into account, unless the covered entity or parent can demonstrate why any legal or other constraints prevent the parent's resources from being available to the covered entity.

36. For purposes of the readily achievable analysis, the covered entity must take into account any and all financial resources available to it, including resources from third parties.

37. This would include any capital or other financial assets, recourse to guarantees that may be used for the covered entity's debt financing or to otherwise assist its business, resources in the form of labor or services, or any other items that would affect the ''overall financial resources'' available to the manufacturer or service provider. Resources of another entity shall be taken into account regardless of whether that other entity is a telecommunications manufacturer or service provider.

38. In some cases, consideration of the resources of another entity may not be applicable because of the nature of the legal relationship between the parties, or because no resources in fact are available to the manufacturer or service provider from the outside entity.

39. In the *NPRM,* we proposed establishing a ''rebuttable presumption'' that reasonably-available resources are those of the covered entity legally responsible for the equipment or service that is subject to the requirements of section 255. After reviewing the record, we have concluded that the better approach is to evaluate the resources of any parent company, or comparable entity with legal obligations to the covered entity, but permit any covered entity (or parent company) to demonstrate why legal or other constraints prevent those resources from being available to the covered entity.

3. Timing of Readily Achievable Assessments

40. The readily achievable obligation imposed by section 255 is both prospective and continuing. While it is appropriate to consider the time needed to incorporate accessibility solutions into new and upgraded products, technological advances that present opportunities for readily achievable accessibility enhancements can occur at any time in a product cycle. A manufacturer's or service provider's obligation to review the accessibility of a product or service, and add accessibility features where readily achievable, is not limited to the initial design stage of a product. We conclude that manufacturers and service providers, at a minimum, must assess whether it is readily achievable to install any accessibility features in a specific product whenever a natural opportunity to review the design of a service or product arises. If it is readily achievable to include an accessibility feature during one of these natural opportunities, the manufacturer or service provider must install the feature. Natural opportunities could include, for example, the redesign of a product model, upgrades of services, significant rebundling or unbundling of product and service packages, or any other modifications to a product or service that require the manufacturer or service provider to substantially re-design the product or service.

4. Documentation of Readily Achievable Assessments

41. As proposed in the *NPRM,* we conclude that we should not at this time delineate specific documentation requirements for ''readily achievable'' analyses. We fully expect, however, that manufacturers and service providers, in the ordinary course of business, will maintain records of their accessibility efforts that can be presented to the Commission to demonstrate compliance with section 255 in the event consumers with disabilities file complaints.

III. Services and Equipment Covered by the Rules

42. Section 255 applies to any ''manufacturer of telecommunications equipment or customer premises equipment'' and to any ''provider of telecommunications service.'' We conclude that, in so far as these phrases are broadly grounded in the Communications Act, our sole task here is to explain their application in the context of section 255. We will, however, as explained below, assert our ancillary jurisdiction to cover two non-telecommunications services.

a. Telecommunications and Telecommunications Service

43. Section 255(c) requires that any ''provider of telecommunications service shall ensure that the service is accessible to and usable by individuals with disabilities, if readily achievable.'' Section 3 of the Act defines ''telecommunications'' as ''the transmission, between or among points specified by the user, of information of the user's choosing, without change in the form or content of the information as sent and received.'' It defines ''telecommunications service'' as ''the offering of telecommunications for a fee directly to the public, or to such classes of users as to be effectively available directly to the public, regardless of the facilities used.''

44. We adopt our tentative conclusion in the *NPRM* that the phrases ''telecommunications'' and ''telecommunications services'' have the general meanings set forth in the Act. Telecommunications services, however, does include services previously classified as adjunct-to-basic. Adjunct-to-basic services are services which literally meet the definition of enhanced services, now called information services, established under the Commission's rules, but which the Commission has determined facilitate the completion of calls through utilization of basic telephone service facilities and are included in the term ''telecommunications services.'' Adjunct-to-basic services include such services as call waiting, speed dialing, call forwarding, computer-provided directory assistance, call monitoring, caller identification, call tracing, and repeat dialing.

45. We decline to expand the meaning of ''telecommunications services'' to include information services for purposes of section 255, as urged by some commenters. In the *NPRM,* we recognized that under our interpretation of these terms, some important and widely used services, such as voicemail

and electronic mail, would fall outside the scope of section 255 because they are considered information services. We conclude, however, that we may not reinterpret the definition of telecommunications services, either for purposes of section 255 only or for all Title II regulation. First, we emphasize that the term ''information services'' is defined separately in the Act. As we noted in the *NPRM,* there was no indication in the legislative history of the 1996 Act that Congress intended these terms to have any different, specialized meaning for purposes of accessibility.

b. Provider of Telecommunications Services

46. We conclude that all entities offering telecommunications services (*i.e.,* whether by sale or resale), including aggregators, should be subject to section 255. An entity that provides both telecommunications and non-telecommunications services, however, is subject to section 255 only to the extent that it provides a telecommunications service.

c. Telecommunications Equipment and Customer Premises Equipment

47. The Act defines ''telecommunications equipment'' as ''equipment, other than customer premises equipment, used by a carrier to provide telecommunications services, and includes software integral to such equipment (including upgrades).'' It defines ''customer premises equipment'' (CPE) as ''equipment employed on the premises of a person (other than a carrier) to originate, route, or terminate telecommunications.''

48. In accordance with the proposal made in the *NPRM,* the express statutory language, and the views of commenters, we find that telecommunications equipment includes software integral to telecommunications equipment. Operation of today's technologically sophisticated telecommunications networks would be impossible without software, and we believe that Congress' decision to expressly clarify that software and upgrades to software are to be considered ''equipment'' acknowledges the important role played by software products. Further, by referencing ''upgrades'' to software as equipment, the definition expressly contemplates that stand-alone software should be considered equipment. For these reasons, we conclude that all software integral to telecommunications equipment is covered by the definition, whether such software is sold with a piece of telecommunications equipment hardware or is sold separately.

49. The statutory definition of CPE under section 3(14) of the Act encompasses all ''equipment employed on the premises of a person (other than a carrier) to originate, route, or terminate telecommunications.'' Although section 3(14) does not specifically reference software integral to CPE, we find, nonetheless, that CPE includes software integral to the operation of the telecommunications functions of the equipment, whether sold separately or not. We note that this conclusion is contrary to our tentative conclusion in the *NPRM* that software sold separately from CPE would not fall within the definition of CPE. After review of the record, however, we are persuaded that stand-alone software that originates, terminates and routes telecommunications should be deemed ''equipment'' under the CPE definition.

50. In connection with multipurpose equipment, we adopt our tentative conclusion that customer premises equipment is covered by section 255 only to the extent that it provides a telecommunications function. Specifically, equipment that generates or receives an electrical, optical or radio signal used to originate, route or terminate telecommunications is covered, even if the equipment is capable of providing non-telecommunications functions. We believe that our interpretation ensures consistency between the obligations of manufacturers to ensure that telecommunications equipment and CPE is designed, developed and fabricated to be accessible, and the obligations of service providers to ensure that the service is accessible.

51. Furthermore, as supported by the record, we conclude that manufacturers will be liable under section 255 for all telecommunications equipment and CPE to the extent that such equipment provides a telecommunications function. In those instances, where a piece of equipment undergoes substantial modifications after its sale, however, we agree with those commenters who argue that it would be unfair to hold the manufacturer liable under section 255. In those instances, which we expect to be infrequent, manufacturers shall bear the burden of proving, by a preponderance of the evidence, that a piece of equipment has undergone substantial modifications after its sale.

d. Manufacturer

52. The Act does not define ''manufacturer of telecommunications or customer premises equipment.'' The Access Board guidelines define a ''manufacturer'' as an entity ''that sells to the public or to vendors that sell to the public; a final assembler.'' This approach, according to the Access Board, would generally cover ''the final assembler of separate subcomponents; that is, the entity whose brand name appears on the product.'' In the NPRM, the Commission proposed to adopt a definition of ''manufacturer'' based upon the Access Board guidelines.

53. In light of our enforcement obligations and based on the record, we now believe that we need a more precise definition of manufacturer than that adopted by the Access Board. In our rules, therefore, we define manufacturer as an entity that makes or produces a product. This definition puts responsibility on those who have direct control over the products produced, and provides a ready point of contact for consumers and the Commission in getting answers to accessibility questions and resolving complaints. We decline to adopt the Access Board's definition because we find that it is so broad that it could include retailers, who simply sell products and may not control any aspect of their actual manufacture.

54. We do not intend this definition to include those who simply sell or distribute a product manufactured by another entity. Nor do we extend the concept of manufacturer to anyone who might modify the equipment before sale to the public. We do not believe as a general matter that retailers, wholesalers, and other post-manufacturing distribution entities can be considered manufacturers who have accessibility obligations under the Act.

55. As supported by the record, we adopt our tentative conclusion to construe section 255 to apply to all manufacturers offering equipment for use in the United States, regardless of their location or national affiliation. Exempting foreign manufacturers would disadvantage American manufacturers, and would deny the American public the full protection section 255 offers.

e. Voicemail and Interactive Menus

56. The record has convinced us that in order for us to carry out meaningfully the accessibility requirements of section 255, requirements comparable to those under section 255 should apply to two information services that are critical to making telecommunications accessible and usable by people with disabilities. We assert ancillary jurisdiction to extend these accessibility requirements to the providers of voicemail and interactive menu service and to the manufacturers of the equipment that

perform those functions. By enacting section 255, Congress has charged the Commission with ensuring that telecommunications services and equipment are accessible to, and usable by, persons with disabilities. We cannot fully achieve that objective without this limited use of our ancillary jurisdiction.

57. We decline to extend accessibility obligations to any other information services. While some commenters have argued that there is an overwhelming need for all information services to be accessible to people with disabilities, we assess the record differently, and use our discretion to reach only those services we find essential to making telecommunications services accessible. Unlike voicemail and interactive menus, other information services discussed by commenters do not have the potential to render telecommunications services themselves inaccessible. Therefore, we decline to exercise our ancillary jurisdiction over those additional services. Many of these other services are alternatives to telecommunications services, but not essential to their effective use. For example, e-mail, electronic information services, and web pages are alternative ways to receive information which can also be received over the phone using telecommunications services. In contrast, inaccessible and unusable voicemail and interactive menus operate in a manner that can render the telecommunications service itself inaccessible and unusable.

IV. Enforcement of Section 255

58. Damages. We adopt our tentative conclusion in the NPRM that damages are available for violations of section 255 or our implementing rules against common carriers. In so holding, we reject the claim that section 255(f)'s preclusion of private rights of action deprives the Commission of any authority to entertain requests for damages by or on behalf of individual complainants.

59. Other Sanctions and Remedies. We affirm our conclusion in the NPRM that we should employ the full range of sanctions and remedies available to us under the Act in enforcing section 255. We conclude that we need not delineate in this Order the various sanctions and remedies available to us under the Act to address violations of section 255 and our rules. We recognize that sanctionable behavior may involve a wide range of conduct by manufacturers and service providers and we will use our considerable discretion to tailor sanctions or remedies to the individual circumstances of a particular violation. While we will view retrofitting as an extreme remedy to be used in egregious cases of willful misconduct, we nevertheless believe that the prospect of such action will serve as a major deterrent to willful and repeated violations of the Act and our rules.

60. We adopt our tentative conclusion in the NPRM that we should encourage consumers to express informally their concerns or grievances about a product to the manufacturer or supplier who brought the product to market before complaining to the Commission. We believe that this policy should apply with equal force to grievances or concerns relating to service providers. We fully expect that many accessibility-related disputes will be satisfactorily resolved through such communications without the need to file complaints. We decline, however, to adopt a rule that would require consumers to contact the manufacturer or service provider about an accessibility barrier before a complaint could be filed with the Commission. Under our section 208 rules, consumers are encouraged but not required to contact the carrier in advance of filing an informal complaint. Our rules governing formal section 208 complaints require both the complainant and defendant to certify, as part of the complaint and answer respectively, that they discussed, or attempted in good faith to discuss, the possibility of settlement with the opposing party prior to filing of the complaint. We conclude that this model is also appropriate for section 255 formal complaints.

61. Form. We adopt our proposal to allow informal complaints all to be transmitted to the Commission by any reasonable means such as by letter, facsimile transmission, voice telephone (voice and TTY), Internet e-mail, audio-cassette recording, and braille.

62. Content. We adopt a rule providing that any section 255 complaint filed with the Commission include: (1) the name and address of the complainant; (2) the name and address of the manufacturer or service provider against whom the complaint is made; (3) details about the equipment or service about which the complaint is made; (4) the date or dates on which the complainant or person on whose behalf the complaint is being filed either purchased, acquired, used or attempted to purchase or use the equipment or service about which the complaint is being made; (5) a statement of facts supporting the complainant's allegation that the equipment or service is not accessible to a person or persons with a disability; (6) the specific relief or satisfaction sought by the complainant; and (7) the complainant's preferred method of response to the complaint (*e.g.*, letter, facsimile transmission, telephone (voice or TTY), Internet e-mail, audio-cassette, braille, or another method that will provide effective communication with the complainant.

63. Standing to File. We conclude that our minimum form and content requirements will alleviate concerns raised by a number of commenters regarding the need for a standing requirement for filing section 255 complaints. The concerns raised by the commenters about possible frivolous complaints are too speculative to warrant a standing requirement where none otherwise exists under our common carrier complaint rules. There is no evidence that frivolous complaints have been a problem under our common carrier rules; nor is there any basis in the record to reasonably conclude that such will be the case for section 255 complaints. In any event, we believe that the minimum content requirements for section 255 complaints will effectively deter the filing of frivolous complaints.

64. Service. We adopt a rule requiring the staff to promptly forward complaints that satisfy our content rules to the manufacturer or service provider involved, along with specific instruction to the defendant company to investigate and attempt to satisfy the complaint within a specified period, generally thirty days. The rule further provides that Commission staff may, in its discretion, request from the defendant company whatever additional information it deems useful to its consideration of the complaint.

65. Designation of Contacts/Agents. We adopt a rule requiring affected manufacturers and service providers to designate an agent or contact whose principal function will be to ensure the manufacturer's or service provider's prompt receipt and handling of accessibility concerns raised by consumers or Commission staff.

66. The Commission will provide access to a listing of the contact representatives or agents designated by manufacturers and service providers. In order to establish this listing, we will require covered manufacturers and service providers to file the required contact information with the Secretary of the Commission within thirty days after the effective date of the rules adopted herein.

67. As a related matter, we note that certain commenters urged that we adopt a requirement that defendant manufacturers and service providers make reasonable, good faith efforts to contact the complainant within five business days of receipt of a complaint

to acknowledge such receipt and discuss how the company intends to proceed with its handling of the complaint. We agree with these commenters that this measure is consistent with our point of contact requirement and will not unduly burden affected companies, and adopt this requirement.

68. Our rules require defendant manufacturers and service providers to prepare their responses in the format requested by the complainant, except where the defendant service provider or equipment manufacturer is incapable of doing so. In cases in which the defendant is incapable of preparing a response using the format requested by the complainant, Commission staff will take actions necessary to ensure that the response is accessible to the complainant.

69. Time to Respond. The commenters are generally supportive of a thirty day period in which to respond to informal complaints, although certain commenters argue that the response should be shortened to 15 days while others favor a longer period of 60–90 days. We believe that a thirty day response period, which mirrors the response time afforded under our common carrier complaint rules, strikes a reasonable balance between our goals of promoting the prompt resolution of accessibility disputes and ensuring that manufacturers and service providers have sufficient time in which to evaluate the complaint and provide meaningful solutions or explanations to consumers.

70. Applicability of §§ 1.720 through 1.736 of the rules. We agree with a number of the commenters that certain accessibility disputes, by their nature or complexity, may not be able to be resolved by the disputing parties. Therefore, we adopt a rule providing that any person seeking formal adjudication of a problem or dispute with a manufacturer or service provider may do so pursuant to the procedures specified under §§ 1.720 through 1.736 of our rules.

71. We conclude that the existing accelerated dispute procedures may be used by the staff for purposes of section 255 formal complaints. Such accelerated procedures will minimize the opportunity for manufacturers and service providers to continue to delay otherwise readily achievable accessibility solutions because the lawfulness of such practices will be subject to expedited review.

72. Eligibility Requirements. Not all accessibility disputes raised in the context of formal complaints will be appropriate for handling under these accelerated procedures. Therefore, we adopt the following requirements that a complainant must satisfy in requesting accelerated resolution of its complaint:

- First, a complainant desiring accelerated dispute resolution must allege in good faith that a person with a disability is not able to access/use particular equipment or services is due to a product's lack of accessibility, and that such lack of access is having or will have an immediate adverse impact on consumers' ability to use the services and equipment covered by our rules.
- Second, the complainant must demonstrate that he or she has contacted or attempted in good faith to contact the manufacturer or service provider against whom the allegations are made and gave or attempted to give the manufacturer or service provider a reasonable period of time (not less than 30 days) to address the problem;
- Third, the complainant must have given prior advance notice to the manufacturer or service provider of its intention to file a formal complaint; and
- Fourth, the complainant must agree to participate in any settlement negotiations scheduled and supervised by Commission staff with respect to the matters alleged in the complaint.

73. Accelerated Dispute Resolution Procedures. Any person with a disability or entity acting on behalf of any such person who satisfies the above-listed conditions may submit its formal complaint, along with a request for accelerated dispute resolution, to the Common Carrier Bureau's Enforcement Division. Where practicable, such complaint and request may be submitted to the Commission by any reasonable means. The filing must include at a minimum: (1) the information described in §§ 1.721 through 1.724 of our rules and (2) a representation by the complainant that the conditions specified in § 1.730 have been met. Complaints accepted for accelerated dispute resolution will be promptly forwarded by the Commission to the named manufacturer or service provider, which shall be called on to answer the complaint in 15 days or such shorter time as the staff may prescribe. Commission staff may, in its discretion, require the complainant and defendant to appear before it, via telephone conference or in person, to bring and give evidence bearing on accessibility, usability or compatibility. In appropriate cases, the staff may schedule and supervise settlement negotiations between the parties.

74. Decisions Issued in Accelerated Proceedings. We adopt a 60-day timetable for issuing a decision in section 255 complaint proceedings under our accelerated procedures. At the same time, we recognize that some disputes that are likely to arise over the proper interpretation and application of our rules will be cases of first impression, the resolution of which may not be possible within the 60 day period. Therefore, staff administering the accelerated docket will have the discretion to extend the 60-day period.

75. We noted in the NPRM that the most common defenses likely to be mounted by manufacturers and service providers in response to either a complaint or an inquiry by the Commission are claims that: (1) the product or service lies beyond the scope of section 255; (2) the product or service is in fact accessible; or (3) accessibility is not readily achievable. We noted that while the first two defenses are relatively straightforward, the readily achievable defense is complex. We therefore proposed to use the Access Board Guidelines applicable to manufacturers as examples of the kinds of compliance measures we would consider in this regard.

76. While we believe some weight should be given to evidence that a respondent made good faith efforts to comply with section 255, we decline to adopt a rule establishing a presumption of compliance in favor of manufacturers and service providers in section 255 complaint actions. Instead, we will review section 255 complaints on a case-by-case basis, giving due consideration to whether the defendant took actions consistent with the rules and guidance we set forth today, as well as any other compliance measures that the respondent has undertaken, such as those set forth in the Access Board's Advisory Appendix.

77. Time Limit for Filing Complaints. We decline to adopt either the 6-month or 1-year limitations period on the filing of section 255 complaints urged by some commenters. We do not agree that a limitations period more restrictive than the 2-years prescribed in section 415 of the Act pertaining to damages claims against common carriers is necessary or desirable to guard against stale or unmeritorious claims.

78. To ensure that this Commission's resources remain properly focused, we adopt a general policy that complaints against manufacturers and service providers determined by the staff to raise issues that are dated or stale due to the passage of time or moot because of industry or product changes (and which do not raise timely damages claims within the meaning of section 415(b)) may, absent indications of an ongoing compliance problem, be subject to summary disposition by the staff.

79. We do not agree with the claim by certain commenters that the five-month complaint resolution deadline imposed on the Commission under section 208(b) of the Act is also applicable to all complaints alleging violations of section 255.

80. We conclude that section 208(b) would apply to a properly filed section 255 formal complaint only to the extent that the complaint raised issues concerning a matter contained in a service provider's tariff or that would have been included in the service provider's tariff but for our forbearance policies.

81. We conclude that our existing rules governing confidential materials adequately address the concerns raised by the commenters and, therefore, do not adopt the additional requirements proposed in the NPRM. As an initial matter, we note that we do not anticipate that confidentiality issues will arise frequently in informal section 255 complaint proceedings. Informal complaint actions, which are exempt proceedings under our ex parte rules, are by nature not designed or intended to facilitate the exchange of confidential information between disputing parties. Defendant manufacturers and service providers are not typically required to submit information designated as confidential or proprietary directly to a complainant; nor is the staff required to transmit confidential information provided by a complainant to a defendant company. To the extent that such information is deemed necessary to the staff's evaluation of an informal complaint, the submitting party may invoke the protection afforded under §§ 0.457 through 0.459 of our rules by clearly designating the information as confidential or proprietary at the time it is submitted to the Commission.

82. Formal complaints filed against common carriers pursuant to §§ 1.720 through 1.736 of our rules are classified as ''restricted'' proceedings under our *ex parte* rules. This ''restricted'' designation, as with other proceedings not designated as exempt or permit-but-disclose, expressly prohibits ex parte presentations in these adjudicatory proceedings from any source. Formal section 255 complaints filed against manufacturers or service providers shall be similarly treated as restricted proceedings.

83. We emphasize that to the extent that compliance issues or problems requiring regulatory intervention are perceived by the staff during the processing of an accessibility-related informal complaint or are otherwise brought to the Commission's attention, the staff will be poised to pursue the matter on its own motion and, when warranted, take or recommend appropriate remedial actions or sanctions from those available to us under the Act and our rules. We reject the suggestion by certain commenters that we establish specific guidelines for initiating investigations and other section 255 enforcement actions on our own motion.

84. As we noted earlier, the Commission has a responsibility to prohibit discrimination on the basis of disability in its programs and activities, as required by the Rehabilitation Act of 1973, as amended. The Commission's rules implementing these responsibilities are set forth at 47 CFR 1.1801 through 1.1870. These requirements apply to the Commission's enforcement provisions and activities. If a member of the public believes that the Commission is not providing equal access to its programs and activities, the procedures for filing a program accessibility complaint are set forth in 47 CFR 1.1870. Complaints regarding access to Commission programs and activities should be sent to the Commission's Office of the Managing Director. Commission staff will provide technical assistance to any member of the public wishing to file a complaint pursuant to §§ 1.1801 through 1.1870 of the rules; regarding access to Commission programs and activities; and any such complaint will not predispose the Commission negatively against any section 255 complaints.

V. Additional Implementation and Enforcement Measures

85. In the NPRM, the Commission sought comment regarding whether existing Commission processes (and associated forms) would be efficient vehicles for any requirements the Commission might develop in this proceeding, such as information collection, or providing notice to firms dealing with the Commission that they may be subject to section 255. The Commission listed the following examples: (1) The Commission's equipment authorization processes under part 2, subpart J of the Commission's rules; (2) equipment import documentation requirements under part 2, subpart K of the rules; (3) licensing proceedings under section 307 of the Act for various radio services used by entities subject to section 255 obligations; and (4) various common carrier filing processes.

86. The Commission also expressed the view that there could be other measures the Commission might take, or might encourage others to take, to foster increased accessibility of telecommunications products such as the establishment of a clearinghouse for current information regarding telecommunications disabilities issues, including product accessibility information, and accessibility solutions.

87. We find that modifying the current equipment certification or other existing Commission processes for purposes of compliance with section 255 is not appropriate. As outlined in the discussion on enforcement and the application of the readily achievable standard, no specific documentation is being required at this time.

88. We believe that the dissemination of technical assistance, including information on product capabilities and availability, as well as information about manufacturer and service provider compliance with section 255, is vitally important. It will both help ensure that people have access to needed products and serve as an enforcement tool. After we determine the best way to present the relevant data, we intend to publish information regarding entities' compliance with these rules. We also intend to provide technical assistance and conduct outreach efforts to inform customers and companies of their rights and responsibilities under these rules.

VI. Procedural Matters

A. Final Regulatory Flexibility Analysis

89. As required by the Regulatory Flexibility Act (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the Notice of Proposed Rulemaking issued in this proceeding. The Commission sought written public comments on the proposals included in the Notice, including comment on the IRFA. This Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

1. Need for and Objectives of the Report and Order and Rules Adopted Therein

90. This rulemaking proceeding was initiated to propose means of implementing and enforcing section 255 of the Communications Act, as added by the Telecommunications Act of 1996. Section 255 is intended to ensure that telecommunications equipment and services will be accessible to persons with disabilities, if such accessibility is readily achievable. If accessibility is not readily achievable, then the telecommunications equipment and services are to be made compatible with specialized customer premises equipment (CPE) or peripheral devices to the extent that so doing is readily achievable.

91. Given the fundamental role that telecommunications has come to play in today's world, we believe that the provisions of section 255 represent the most significant governmental action for people with disabilities since the passage of the Americans with Disabilities Act of 1990 (ADA). Inability to use telecommunications equipment and services can be life-threatening in emergency situations, can severely limit educational and employment opportunities, and can otherwise interfere with full participation in business, family, social, and other activities. We must do all we can to ensure that people with disabilities are not left behind in the telecommunications revolution and consequently isolated from contemporary life.

92. In the Notice, we set forth proposals to implement and enforce the requirement in section 255 that telecommunications offerings be accessible to the extent readily achievable. We proposed a ''fast-track'' process for resolving accessibility complaints informally and quickly and more conventional remedial processes for cases where fast-track solutions are not possible, or where there appears to be an underlying noncompliance with section 255. We noted that, in either case, we would look favorably upon demonstrations by companies that they had considered accessibility throughout the development of telecommunications products when assessing whether service providers and equipment manufacturers have met their accessibility obligations under section 255. In the accompanying Report and Order we have made the following decisions.

(1) We have incorporated most of the Access Board guidelines into our rules with two minor exceptions and have applied them to the services covered;

(2) We have asserted our ancillary jurisdiction to extend section 255's coverage to voicemail and interactive menu services and service providers and equipment used to provide these services;

(3) We have clarified that section 255 applies to each piece of equipment and all service offerings, but have noted that the industry has the discretion to determine which accessibility features should be incorporated in all products and which ones can be less than universally deployed, so long as all that is readily achievable is done; and

(4) We have adopted enforcement rules patterned after our long-standing rules governing complaints filed against common carriers under section 208 of the Act, with certain modifications we have concluded are necessary to fulfill the goals of section 255.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

93. We noted in the IRFA that the resources of the regulated entity are taken into account in the determination of whether accessibility of a given product or service is readily achievable and that there is thus an inherent consideration of the financial burden on the entity in its obligation to provide accessibility: if not readily achievable, the obligation is removed. Nevertheless, we acknowledged that all regulated entities would be required to assess whether providing accessibility is readily achievable and that an important issue for RFA purposes is thus not the absolute cost of providing accessibility, but, rather, the extent to which the cost of performing an assessment as to whether an accessibility feature is readily achievable is unduly burdensome on small entities.

94. We received four comments specifically captioned as being in response to the IRFA. In its comments to the IRFA, CEMA states that ''the Commission must take all steps necessary to ensure that any Section 255 implementation rules are not unduly burdensome to small manufacturers; it should also adopt those rules that serve to minimize the economic impact of this rulemaking on small entities.'' Lucent's comments question the apparent conflict between § 1193.43 of the Access Board's Guidelines and § 68.317 of the Commission's rules dealing with telephone volume control standards, especially in view of the Commission's tentative conclusion in the Notice that the Access Board's Guidelines do not overlap, duplicate or conflict with existing Commission Rules. Motorola comments that the Fast Track process imposes a substantial information collection requirement on manufacturers at each decisional point in the product design, development and fabrication process. Both Motorola and TIA contend that the cost of this information collection requirement should be considered as part of the readily achievable analysis. We believe that the information collection requirement on manufacturers has been minimized by the implementation of informal complaint procedures.

C. Description and Estimate of the Number of Small Entities to Which the Rules Adopted in the Report and Order Will Apply

93. The RFA directs agencies to provide a description and, where feasible, an estimate of the number of small entities that may be affected by the rules adopted in the accompanying Report and Order. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). A small organization is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of 1992, there were approximately 275,801 small organizations.

96. The rules adopted in the Report and Order will apply to manufacturers of telecommunications equipment and CPE to the extent it provides telecommunications, voicemail and interactive menu functions. In addition, telecommunications service providers of many types will be affected, including wireline common carriers and commercial mobile radio service (CMRS) providers. To the extent that software performs a telecommunication function, software developers or manufacturers may also be affected. We have described and estimated the number of small entity licensees and other covered entities that may be affected by the rules adopted in the Report and Order.

97. Equipment Manufacturers. The following chart contains estimated numbers of domestic entities that may be affected by the rules promulgated in this proceeding. It is based, in part, on firm counts that reflect product lines not involved in telecommunications, as defined by the 1996 Act, and reflects overlapping firm counts and firm counts that have been deliberately commingled to avoid disclosing the value of individual firms' equipment shipments for the reporting period.

Product class/ code	Product description	Estimated firm count
3571 ..	Personal computer, terminals and workstations.	546
3661 ..	Telephone and telegraph equipment.	540
3663 ..	Communications systems and equipment.	938

Product class/ code	Product description	Estimated firm count
3577 ..	Computer peripheral equipment, not elsewhere classified.	259
3577 ..	Parts and subassemblies for computer peripherals and input/output equipment.	72

98. Software Manufacturers. We sought comment in the IRFA on the impact of our proposed rules on the small businesses within this industrial category. No comments on this issue were forthcoming. The SBA has two small business size standard to be used for software publishers: (1) Entities that design, develop or produce prepackaged software have a size standard of $18 million in average annual revenues; and, (2) entities that sell existing, off-the-shelf prepackaged software as a finished product have a size standard of 500 employees or less. According to the Software Information Industry Association (SIIA), there are approximately 8,000 publishers of packaged software. Of these 8,000, we estimate that only about 500 are involved in the production of software specific to telecommunications. We do not have information on the number of these publishers that are not independently owned and operated, or have more than 1,500 employees, and thus are unable at this time to estimate with greater precision the number of software publishers that would qualify as small business concerns under the SBA definition. Consequently, we estimate that there are equal to or fewer than 500 telecommunications software publishers that will be affected by section 255.

99. Telecommunications Service Entities. The United States Bureau of the Census reports that, at the end of 1992, there were 3,497 firms engaged in providing telephone services for at least one year. This number contains a variety of different categories of carriers, including LECs, IXCs, CAPs, cellular carriers, other mobile service carriers, operator service providers, pay telephone providers, personal communications services (PCS) providers, covered specialized mobile radio (SMR) providers, and resellers. In the IRFA, we noted that some of those 3,497 telephone service firms may not qualify as small entities or small incumbent LECs because they are not ''independently owned and operated.'' As an example, we cited a PCS provider that is affiliated with an IXC having more than 1,500 employees and tentatively concluded that fewer than 3,497 telephone service firms are small entity telephone service firms or small incumbent LECs.

100. According to the Telecommunications Industry Revenue: Telecommunications Relay Service Fund Worksheet Data (TRS Worksheet), there are 3,604 interstate carriers. These carriers include, inter alia, LECs, wireline carriers and service providers, IXCs, CAPs, operator service providers, pay telephone providers, providers of telephone toll service, providers of telephone exchange service, and resellers. In the IRFA we sought information regarding how many providers of telecommunications services, existing and potential, are considered small businesses. We did not receive comment on this issue, so we conclude that this data is acceptable to the industry. We noted that the SBA has defined a small business for Radiotelephone Communications (SIC 4812) and Telephone Communications, Except Radiotelephone (SIC 4813), as a small entities having no more than 1,500 employees, and sought comment as to whether this definition is appropriate for our purposes here. Additionally, we requested that each commenter identify whether it is a small business under this definition and, if a subsidiary of another entity, provide this information for both itself and its parent corporation or entity.

101. Wireline Carriers and Service Providers. The Census Bureau reports that there were 2,321 such telephone companies in operation for at least one year at the end of 1992. According to the SBA definition, a small business telephone company other than a radiotelephone company is one employing no more than 1,500 persons. All but 26 of the 2,321 non-radiotelephone companies listed by the Census Bureau were reported to have fewer than 1,000 employees.

102. Thus, even if all 26 of those companies had more than 1,500 employees, there would still be 2,295 non-radiotelephone companies that might qualify as small entities or small incumbent LECs. We noted in the IRFA that we did not have information regarding which of these carriers are not independently owned and operated, and thus were unable to estimate with greater precision the number of wireline carriers and service providers that would qualify as small business concerns under the SBA definition. Consequently, we estimated that there are fewer than 2,295 small telephone communications companies other than radiotelephone companies.

103. Incumbent Local Exchange Carriers. Neither the Commission nor the SBA has developed a definition for small providers of local exchange services. The closest applicable definition under the SBA rules is for telephone communications companies other than radiotelephone (wireless) companies. The most reliable source of information of which we are aware regarding the number of LECs nationwide appears to be the data that we collect annually in connection with the TRS Worksheet. According to our most recent data, 1,410 companies reported that they were engaged in the provision of local exchange services. Although it seems certain that some of these carriers are not independently owned and operated, or have more than 1,500 employees, we are unable at this time to estimate with greater precision the number of LECs that would qualify as small business concerns under the SBA definition. Consequently, we estimate that there are equal to or fewer than 1,410 small incumbent LECs. Because the small incumbent LECs subject to these rules are either dominant in their field of operations or are not independently owned and operated, they would be excluded from the definition of ''small entity'' and ''small business concern,'' consistent with our prior practice.

104. Interexchange Carriers. Neither the Commission nor SBA has developed a definition of small entities specifically applicable to providers of interexchange services. The closest applicable definition under the SBA rules is for telephone communications companies except radiotelephone (wireless) companies. The most reliable source of information regarding the number of IXCs nationwide is the data that we collect annually in connection with the TRS Worksheet. According to our most recent data, 151 companies reported that they were engaged in the provision of interexchange services. We do not have information on the number of these carriers that are not independently owned and operated, or have more than 1,500 employees, and thus we are unable at this time to estimate with greater precision the number of IXCs that would qualify as small business concerns under the SBA definition. Consequently, we estimate that there are equal to or fewer than 151 small entity IXCs.

105. Competitive Access Providers and Competitive Local Exchange Carriers. Neither the Commission nor SBA has developed a definition of small entities specifically applicable to providers of competitive access services (CAPs) and competitive local exchange

carriers (CLECs). The closest applicable definition under the SBA rules is for telephone communications companies except radiotelephone (wireless) companies. The most reliable source of information regarding the number of CAPs and CLECs nationwide is the data that we collect annually in connection with the TRS Worksheet. According to our most recent data, 129 companies reported that they were engaged in the provision of competitive access services. We do not have information on the number of these carriers that are not independently owned and operated, or have more than 1,500 employees, and thus are unable at this time to estimate with greater precision the number of CAPs and CLECs that would qualify as small business concerns under the SBA definition. Consequently, we estimate that there are equal to or fewer than 129 small CAPs and CLECs.

106. Operator Service Providers. Carriers engaged in providing interstate operator services from aggregator locations (OSPs) currently are required under section 226(b)(1)(D) of the Communications Act of 1934, as amended, 47 U.S.C. S 226, to ensure that each aggregator for which such provider is the presubscribed OSP is in compliance with the posting required of such aggregator. OSPs also are required under section 226 to file and maintain informational tariffs at the Commission. The number of such tariffs on file appears to be the most reliable source of information of which we are aware regarding the number of OSPs nationwide, including small business concerns, that will be affected by decisions and rules adopted in this Second Report and Order. As of July 12, 1999, approximately 760 carriers had informational tariffs on file at the Commission. The SBA has developed a definition of small entities for telecommunications companies other than radiotelephone (wireless) companies (Telephone Communications, Except Radiotelephone). According to the SBA's definition, a small business telephone company other than a radiotelephone company is one employing no more than 1,500 persons. Although it seems certain that some of these entities are not independently owned and operated, or have more than 1,500 employees, we are unable at this time to estimate with greater precision the number of OSPs that would qualify as small business concerns under SBA's definition. Consequently, we estimate that there are fewer than 760 small entity OSPs that may be affected by the decisions and rules adopted in this Report and Order.

107. Pay Telephone Providers. Neither the Commission, nor SBA has developed a definition of small entities specifically applicable to pay telephone providers. The closest applicable definition under SBA rules is for telephone communications companies except radiotelephone (wireless) companies. The most reliable source of information regarding the number of pay telephone providers nationwide is the data that we collect annually in connection with the TRS Worksheet. According to our most recent data, 509 companies reported that they were engaged in the provision of pay telephone services. We do not have information on the number of these carriers that are not independently owned and operated, or have more than 1,500 employees, and thus are unable at this time to estimate with greater precision the number of pay telephone providers that would qualify as small business concerns under SBA definition. Consequently, we estimate that there are equal to or fewer than 509 small pay telephone providers.

108. Resellers (Including Debit Card Providers). Neither the Commission, nor SBA has developed a definition of small entities specifically applicable to resellers. The closest applicable SBA definition for a reseller is a telephone communications company except radiotelephone (wireless) companies. The most reliable source of information regarding the number of resellers nationwide is the data that the Commission collects annually in connection with the TRS Worksheet. According to our most recent data, 369 companies report that they are engaged in the resale of telephone service. We do not have information on the number of these carriers that are not independently owned and operated, or have more than 1,500 employees, and thus we are unable at this time to estimate with greater precision the number of resellers that would qualify as small entities or small incumbent LEC concerns under the SBA definition. Consequently, we estimate that there are equal to or fewer than 369 small entity resellers.

109. 800 and 800-Like Service Subscribers. Neither the Commission, nor the SBA has developed a definition of small entities specifically applicable to 800 and 800-like service (''toll free'') subscribers. The most reliable source of information regarding the number of these service subscribers appears to be data the Commission collects on the 800, 888, and 877 numbers in use. According to our most recent data, at the end of January 1999, the number of 800 numbers assigned was 7,692,955; the number of 888 numbers that had been assigned was 7,706,393; and the number of 877 numbers assigned was 1,946,538. We do not have data specifying the number of these subscribers that are not independently owned and operated or have more than 1,500 employees, and thus are unable at this time to estimate with greater precision the number of toll free subscribers that would qualify as small business concerns under the SBA's definition. Consequently, we estimate that there are fewer than 7,692,955 small entity 800 subscribers, fewer than 7,706,393 small entity 888 subscribers, and fewer than 1,946,538 small entity 877 subscribers.

110. International Service Providers. The Commission has not developed a definition of small entities applicable to licensees in the international services. Therefore, the applicable definition of small entity is the definition under the SBA rules applicable to Communications Services, Not Elsewhere Classified (NEC). This definition provides that a small entity is one with $11.0 million or less in average annual receipts. According to the Census Bureau, there were a total of 848 communications services, NEC, in operation in 1992, and a total of 775 had annual receipts of less than $9.999 million. The Census report does not provide more precise data. Many of these services do not have specified uses and it is uncertain, at this point in time, whether they will ultimately provide telecommunications services.

111. International Public Fixed Radio (Public and Control Stations). Commission records show there are 3 licensees in this service. We do not request or collect annual revenue information, and thus are unable to estimate the number of international public fixed radio licensees that would constitute a small business under the SBA definition. Consequently, we estimate that there are equal to or fewer than 3 small entities that are international public fixed radio licensees.

112. Fixed Satellite Transmit/Receive Earth Stations and Fixed Satellite Small Transmit/Receive Earth Stations. Based on actual payments, there are approximately 3,100 earth station authorizations, a portion of which are Fixed Satellite Transmit/Receive Earth Stations and a portion of which are Fixed Satellite Small Transmit/Receive Earth Stations. We do not request or collect annual revenue information, and thus are unable to estimate the number of the earth stations of either category that would be owned by a small

business under the SBA definition. Consequently, we estimate that there are equal to or fewer than 3,100 small entities that hold such authorizations.

113. Fixed Satellite Very Small Aperture Terminal (VSAT) Systems. These stations operate on a primary basis, and frequency coordination with terrestrial microwave systems is not required. Thus, a single ''blanket'' application may be filed for a specified number of small antennas and one or more hub stations. The Commission has processed 377 applications. We do not request or collect annual revenue information, and thus are unable to estimate the number of VSAT systems that would be owned by a small business under the SBA definition. Consequently, we estimate that there are equal to or fewer than 377 small entities that hold such authorizations.

114. Mobile Satellite Earth Stations. There are 11 licensees. We do not request or collect annual revenue information, and thus are unable to estimate whether either of these licensees would constitute a small business under the SBA definition. Consequently, we estimate that there are 11 or less small entities that hold such licenses.

115. Space Stations (Geostationary). There are 43 space station licensees. We do not request or collect annual revenue information, and thus are unable to estimate the number of geostationary space stations that would be owned by a small business under the SBA definition. Consequently, we estimate that there are equal to or fewer than 43 small entities that hold such licenses.

116. Space Stations (Non-Geostationary). There are twelve Non-Geostationary Space Station licensees, of which only two systems are operational. We do not request or collect annual revenue information, and thus are unable to estimate the number of non-geostationary space stations that would be owned by a small business under the SBA definition. Consequently, we estimate that there are twelve or less small entities that hold such licenses.

117. Mobile Satellite Services (MSS). Mobile Satellite Services or Mobile Satellite Earth Stations are intended to be used while in motion or during halts at unspecified points. These stations operate as part of a network that includes a fixed hub or stations. The stations that are capable of transmitting while a platform is moving are included under section 20.7(c) of the Commission's rules as mobile services within the meaning of sections 3(27) and 332 of the Communications Act. Those MSS services are treated as CMRS if they connect to the Public Switched Network (PSN) and also satisfy other criteria in Section 332. Facilities provided through a transportable platform that cannot move when the communications service is offered are excluded from section 20.7(c) of the rules.

118. The MSS networks may provide a variety of land, maritime and aeronautical voice and data services. There are eight mobile satellite licensees. At this time, we are unable to make a precise estimate of the number of small businesses that are mobile satellite earth station licensees and could be considered CMRS providers of telecommunications service. Consequently, we estimate that there eight or less small entities that hold such licenses.

119. Wireless Telecommunications Service Providers. The Commission has not yet developed a definition of small entities with respect to the provision of CMRS services. Therefore, for CMRS providers not falling within any other established SBA category (i.e., Radiotelephone Communications or Telephone Communications, Except Radiotelephone), the applicable definition of a small entity would be the SBA definition applicable to the ''Communications Services, Not Elsewhere Classified.'' This definition provides that a small entity is one with $11.0 million or less in average annual receipts. The Census Bureau estimates indicate that of the 848 firms in the ''Communications Services, Not Elsewhere Classified'' category, 775 are small businesses. It is not possible to predict which of these would be small entities (in absolute terms or by percentage) or to classify the number of small entities by particular forms of service.

120. Cellular Radio Telephone Service. The Commission has not developed a definition of small entities specifically applicable to cellular licensees. Therefore, the applicable definition of a small entity is the SBA definition applicable to radiotelephone companies, which provides that a small entity is a radiotelephone company employing no more than 1,500 persons. The size data provided by SBA do not enable us to make a meaningful estimate of the number of cellular providers that are small entities because it combines all radiotelephone companies with 500 or more employees. We therefore have used the 1992 Census of Transportation, Communications, and Utilities, conducted by the Bureau of the Census, which is the most recent information available. That census shows that only 12 radiotelephone firms out of a total of 1,178 such firms operating during 1992 had 1,000 or more employees. Therefore, even if all 12 of these large firms were cellular telephone companies, all of the remainder would be small businesses under the SBA definition.

121. There are presently 1,758 cellular licenses. However, the number of cellular licensees is not known, since a single cellular licensee may own several licenses. In addition, we note that there are 1,758 cellular licenses; however, a cellular licensee may own several licenses. In addition, according to the most recent Telecommunications Industry Revenue data, 732 carriers reported that they were engaged in the provision of either cellular service or Personal Communications Service (PCS) services, which are placed together in the data. We do not have data specifying the number of these carriers that are not independently owned and operated or have more than 1,500 employees, and thus are unable at this time to estimate with greater precision the number of cellular service carriers that would qualify as small business concerns under the SBA's definition. Consequently, we estimate that there are 732 or fewer small cellular service carriers that may be affected by the rules, herein adopted.

122. Broadband Personal Communications Service. The broadband PCS spectrum is divided into six frequency blocks designated A through F, and the Commission has held auctions for each block. The Commission defined ''small entity'' for Blocks C and F as an entity that has average gross revenues of less than $40 million in the three previous calendar years. For Block F, an additional classification for ''very small business'' was added and is defined as an entity that, together with their affiliates, has average gross revenues of not more than $15 million for the preceding three calendar years. These regulations defining ''small entity'' in the context of broadband PCS auctions have been approved by the SBA. No small businesses within the SBA-approved definition bid successfully for licenses in Blocks A and B. There were 90 winning bidders that qualified as small entities in the Block C auctions. A total of 93 small and very small business bidders won approximately 40% of the 1,479 licenses for Blocks D, E, and F. Based on this information, we conclude that the number of small broadband PCS licensees will include the 90 winning C Block bidders and the 93 qualifying bidders in the D, E, and F blocks, for a total of 183 small entity PCS providers

as defined by the SBA and the Commission's auction rules.

123. Narrowband PCS. The Commission has auctioned nationwide and regional licenses for narrowband PCS. There are 11 nationwide and 30 regional licensees for narrowband PCS. The Commission does not have sufficient information to determine whether any of these licensees are small businesses within the SBA-approved definition for radiotelephone companies. At present, there have been no auctions held for the major trading area (MTA) and basic trading area (BTA) narrowband PCS licenses. The Commission anticipates a total of 561 MTA licenses and 2,958 BTA licenses will be awarded by auction. Such auctions have not yet been scheduled, however. Given that nearly all radiotelephone companies have no more than 1,500 employees and that no reliable estimate of the number of prospective MTA and BTA narrowband licensees can be made, we assume, for purposes of this IRFA, that all of the licenses will be awarded to small entities, as that term is defined by the SBA.

124. Specialized Mobile Radio. Pursuant to section 90.814(b)(1) of the Commission's Rules, the Commission has defined ''small entity'' for geographic area 800 MHz and 900 MHz SMR licenses as a firm that had average gross revenues of less than $15 million in the three previous calendar years. This regulation defining ''small entity'' in the context of 800 MHz and 900 MHz SMR has been approved by SBA. The rules promulgated in the Report and Order may apply to SMR providers in the 800 MHz and 900 MHz bands. We do not know how many firms provide 800 MHz or 900 MHz geographic area SMR service, or how many of these providers have average annual gross revenues of less than $15 million.

125. The Commission recently held auctions for geographic area licenses in the 900 MHz SMR band. There were 60 winning bidders who qualified as small entities under the Commission's definition in the 900 MHz auction. Based on this information, we conclude that the number of geographic area SMR licensees affected by the rules promulgated in the Report and Order includes these 60 small entities.

126. Based on the auctions held for 800 MHz geographic area SMR licenses, there are 10 small entities currently holding 38 of the 524 licenses for the upper 200 channels of this service. However, the Commission has not yet determined how many licenses will be awarded for the lower 230 channels in the 800 MHz geographic area SMR auction. There is no basis to estimate, moreover, how many small entities within the SBA definition will win these licenses. Given the facts that nearly all radiotelephone companies have fewer than 1,000 employees and that no reliable estimate of the number of prospective 800 MHz SMR licensees can be made, we assume, for purposes of our evaluations and conclusions in this FRFA, that all of the licenses will be awarded to small entities, as that term is defined by SBA.

127. 220 MHz Radio Service—Phase I Licensees. The 220 MHz service has both Phase I and Phase II licenses. Phase I licensing was conducted by lotteries in 1992 and 1993. There are approximately 1,515 such non-nationwide licensees and four nationwide licensees currently authorized to operate in the 220 MHz band. The Commission has not developed a definition of small entities specifically applicable to such incumbent 220 MHz Phase I licensees. To estimate the number of such licensees that are small businesses, we apply the definition under the SBA rules applicable to Radiotelephone Communications companies. This definition provides that a small entity is a radiotelephone company employing no more than 1,500 persons. According to the Bureau of the Census, only 12 radiotelephone firms out of a total of 1,178 such firms which operated during 1992 had 1,000 or more employees. Therefore, if this general ratio continues in 1999 in the context of Phase I 220 MHz licensees, we estimate that nearly all such licensees are small businesses under the SBA's definition.

128. 220 MHz Radio Service—Phase II Licensees. The Phase II 220 MHz service is a new service, and is subject to spectrum auctions. In the 220 MHz Third Report and Order, we adopted criteria for defining small businesses and very small businesses for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. We have defined a small business as an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding $15 million for the preceding three years. Additionally, a very small business is defined as an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than $3 million for the preceding three years. The SBA has approved these definitions. An auction of Phase II licenses commenced on September 15, 1998, and closed on October 22, 1998. Nine hundred and eight (908) licenses were auctioned in 3 different-sized geographic areas: three nationwide licenses, 30 Regional Economic Area Group Licenses, and 875 Economic Area (EA) Licenses. Of the 908 licenses auctioned, 693 were sold. Companies claiming small business status won: one of the Nationwide licenses, 67% of the Regional licenses, and 54% of the EA licenses. As of January 22, 1999, the Commission announced that it was prepared to grant 654 of the Phase II licenses won at auction. A re-auction of the remaining, unsold licenses was completed on June 30, 1999, wherein 222 of the remaining licenses were sold, but have yet to be licensed.

129. Paging. To ensure the more meaningful participation of small business entities in the auctions, the Commission adopted a two-tiered definition of small businesses in the Paging Second Report and Order, stating that: (1) An entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than $3 million; or (2) an entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than $15 million. In December 1998, the Small Business Administration approved the two-tiered size standards for paging services set forth in the Second Report and Order.

130. *MEA and EA Licenses.* In the Final Regulatory Flexibility Analysis incorporated in Appendix C of the Second Report and Order, the Commission anticipated that approximately 16,630 non-nationwide geographic area licenses will be auctioned. While we are unable to predict accurately how many paging licensees meeting one of the above definitions will participate in or be successful at auction, our Third CMRS Competition Report estimated that, as of January 1998, there were more than 600 paging companies in the United States. The Third CMRS Competition Report also indicates that at least ten of the top twelve publicly held paging companies had average gross revenues in excess of $15 million for the three years preceding 1998. The Commission expects that these ten companies will participate in the paging auction and may employ the partitioning or disaggregation rules. The Commission also expects, for purposes of the evaluations and conclusions in this Final Regulatory Flexibility Analysis, that a number of paging licenses will be awarded to small businesses, and at least some of those small business licensees will likely also take advantage of the partitioning and disaggregation rules. We are unable to predict accurately the number of small

businesses that may choose to acquire partitioned or disaggregated MEA or EA licenses. The Commission expects, however, that entities meeting one of the above definitions will use partitioning and disaggregation as a means to obtain a paging license from an MEA or EA licensee at a cost lower than the cost of the license for the entire MEA or EA.

131. *Nationwide Geographic Area Licenses.* The partitioning and disaggregation rules pertaining to nationwide geographic area licenses will affect the 26 licensees holding nationwide geographic area licenses to the extent they choose to partition or disaggregate, as well as any entity that enters into a partitioning or disaggregation agreement with a nationwide geographic area licensee. No parties, however, commented on the number of small business nationwide geographic area licensees that might elect to partition or disaggregate their licenses and no reasonable estimate can be made. While we are unable to state accurately how many nationwide geographic area licensees meet one of the above small business definitions, our Third CMRS Competition Report indicates that at least eight of the top twelve publicly held paging companies hold nationwide geographic area licenses and had average gross revenues in excess of $15 million for the three years preceding 1998. The Commission expects at least some of these eight companies to employ the partitioning or disaggregation rules, and also expects, for the purposes of evaluations and conclusions in this Final Regulatory Flexibility Analysis, that nationwide geographic area licensees meeting one of the above definitions may use the partitioning or disaggregation rules. While we are unable to predict accurately the number of small businesses that may choose to acquire partitioned or disaggregated licenses from nationwide geographic area licensees, the Commission expects, for purposes of the evaluations and conclusions in the Final Regulatory Flexibility Analysis, that entities meeting one of the above small business definitions will use partitioning and disaggregation as a means to obtain a paging license from a nationwide geographic area licensee.

132. Air-Ground Radiotelephone Service. The Commission has not adopted a definition of small business specific to the Air-Ground Radiotelephone Service, which is defined in Section 22.99 of the Commission's rules. Accordingly, we will use the SBA definition applicable to radiotelephone companies, *i.e.*, an entity employing no more than 1,500 persons. There are approximately 100 licensees in the Air-Ground Radiotelephone Service, and we estimate that almost all of them qualify as small under the SBA definition.

133. Local Multipoint Distribution Service (LMDS). LMDS licensees may use spectrum for any number of services. We anticipate that the greatest intensity of use will be for either radio telephone or pay television services. SBA has developed definitions applicable to each of these services; however, because pay television is not a telecommunications service subject to section 255, that definition is not relevant to this FRFA. The Commission has adopted a definition of small entities applicable to LMDS licensees, which is a new service. In the LMDS Order we adopted criteria for defining small businesses for determining bidding credits in the auction, but we believe these criteria are applicable for evaluating the burdens imposed by section 255. We defined a small business as an entity that, together with affiliates and controlling principals, has average gross revenues not exceeding $40 million for the three preceding years. Additionally, small entities are those which together with their affiliates and controlling principals, have average gross revenues for the three preceding years of more than $40 million but not more than $75 million. This definition has been approved by the SBA. Upon completion of the LMDS auction, 93 of the 104 bidders qualified as small entities, smaller businesses, or very small businesses. These 93 bidders won 664 of the 864 licenses. We estimate that all of these 93 bidders would qualify as small under the SBA definitions, but cannot yet determine what percentage would be offering telecommunications services subject to the requirements of section 255.

134. Rural Radiotelephone Service. The Commission has not adopted a definition of a small entity specific to the Rural Radiotelephone Service. A significant subset of the Rural Radiotelephone Service is the Basic Exchange Telephone Radio Systems (BETRS). Thus, we will use the SBA's definition applicable to radiotelephone companies, *i.e.*, an entity employing no more than 1,500 persons. There are approximately 1,000 licensees in the Rural Radiotelephone Service, and we estimate that almost all of them qualify as small entities under the SBA's definition.

135. Wireless Communications Services. This service can be used for fixed, mobile, radiolocation and digital audio broadcasting satellite uses. The Commission defined small business for the wireless communications services (WCS) auction as an entity with average gross revenues of $40 million for each of the three preceding years, and a very small business as an entity with average gross revenues of $15 million for each of the three preceding years. In the auction, there were seven winning bidders that qualified as very small business entities, and one that qualified as a small business entity. We conclude that the number of geographic area WCS licensees affected includes these eight entities.

136. 39 GHz Band. In the 39 GHz Band NPRM and Order, we proposed to define a small business as an entity that, together with its affiliates and attributable investors, has average gross revenues for the three preceding years of less than $40 million. We have not yet received approval by the SBA for this definition. Therefore, the applicable definition of a small entity is the SBA definition applicable to radiotelephone companies, which is a radiotelephone company employing no more than 1,500 persons. As noted previously, the 1992 Census of Transportation, Communications, and Utilities, conducted by the Bureau of the Census, shows that only 12 radiotelephone firms out of a total of 1,178 such firms which operated during 1992 had 1,000 or more employees. Therefore, a majority of 39 GHz entities providing radiotelephone services could be small businesses under the SBA definition, and we assume, for purposes of our evaluation here, that nearly all of the 39 GHz licensees will be small entities, as that term is defined by the SBA.

D. Summary of Projected Reporting, Recordkeeping, and Other Compliance Requirements

137. As we have noted, the objective of section 255 is to give persons with disabilities increased access to telecommunications. Both equipment manufacturers and telecommunications service providers are obligated to provide accessibility for persons with any one or more different disabilities to the extent that it is readily achievable for them to do so. In the broadest sense, compliance consists of an on-going, disciplined, and systematic effort to provide the greatest level of accessibility.

138. We have declined to adopt suggestions that we require manufacturers and service providers to establish specific internal systems and recordkeeping practices for purposes of responding to section 255 complaints and inquiries or require manufacturers to maintain public files recording their

compliance with section 255 and our rules. We see no need to burden manufacturers and service providers with detailed processing and reporting requirements which could hinder rather than hasten the resolution of accessibility disputes. The only reporting requirement imposed by the rules is that each covered entity designate an agent or contact whose principal function will be to ensure the manufacturer's or service provider's prompt receipt and handling of accessibility concerns raised by consumers or Commission staff. We proposed this requirement in the Notice, and it received universal support among the commenters.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities Consistent with Stated Objectives, and Significant Alternatives Considered

139. We noted in the IRFA that the resources of the regulated entity are taken into account in the determination of whether accessibility of a given product or service is readily achievable and that there is thus an inherent consideration of the financial burden on the entity in its obligation to provide accessibility: if not readily achievable, that obligation is removed. Nevertheless, we acknowledged that all regulated entities would be required to assess whether providing accessibility is readily achievable and that an important issue for RFA purposes is thus not the absolute cost of providing accessibility, but, rather, the extent to which the cost of performing an assessment as to whether an accessibility feature is readily achievable is unduly burdensome on small entities.

140. As early as the Notice of Inquiry, we sought comment on three possible approaches for implementing and enforcing the provisions of section 255: (1) Case-by-case determinations; (2) guidelines or a policy statement; or (3) rules setting forth procedural or performance requirements intended to promote accessibility. The Notice focused principally on procedural requirements as a practical, common sense means to ensure that consumers with disabilities would have access to telecommunications services and equipment. In the Notice we considered using case-by-case determinations exclusively, in lieu of any rules, but tentatively discarded this approach because we believed that in a rapidly changing market with unpredictable technological breakthroughs, the slow development of case law would be insufficient to guide covered entities and to provide an understanding of their accessibility obligations.

141. We also considered issuing guidelines or a policy statement, but tentatively discarded this approach, as well, because of our view that a greater degree of regulatory and administrative certainty would best serve the interests of both consumers and businesses that must comply with section 255. Although we acknowledged that a policy statement might serve the purpose of informing case-by-case determinations in complaint proceedings and lend some predictability to the process, we tentatively decided that, in order for accessibility to be addressed in a pro-active manner, equipment manufacturers and service providers should have clear expressions of the demands that section 255 places on their operations before the beginning of the design process. Therefore, we tentatively concluded that the potential drawbacks of exclusive reliance on case-by-case determinations as a means of implementing section 255 would not be sufficiently diminished by the adoption of guidelines or a policy statement.

142. We also considered and tentatively rejected the option of promulgating specific performance requirements. Such an approach, under which the Commission would attempt to establish an array of specific parameters for features and functions across a broad range of telecommunications services and equipment, was viewed as potentially burdensome to covered entities. We also considered it to be fraught with other potential problems, such as rapid changes in technology, that would require frequent revision of the performance requirements and could cause confusion in the telecommunications marketplace. We tentatively decided that the promulgation of specific rules governing the design process would also impose burdens on covered entities whose resources would be better spent in achieving and improving accessibility.

143. As a result of our tentative decision to rely primarily on procedural rules, we took several steps in the Notice to minimize the burdens on all regulated entities. First, we sought to provide incentives to industry for early and on-going consideration of accessibility issues by indicating that we would look favorably upon efforts to implement the Access Board's guidelines by such means as formalizing self-assessment, external outreach, internal management, and user information and support to address accessibility issues. Second, we attempted to unravel the statutory terminology to give guidance on the interpretation of key language within the telecommunications context. Third, we proposed a two-phase process for dealing with section 255 consumer complaints. In the first phase, which we referred to as the ''fast-track,'' we proposed that Commission staff be required to refer any complaint or inquiry to the manufacturer or service provider concerned, who would have a period of five business days to address the problem. Where fast-track efforts failed to produce a satisfactory solution, we proposed to apply complaint processes similar to those used in section 208 complaint proceedings.

144. Although we initially viewed the ''fast-track'' process as an efficient, consumer-friendly means of dealing with problems associated with accessibility compliance, parties representing both consumer and industry interests criticized the proposed mandatory ''fast-track'' mechanism as burdensome and confusing and agreed that our section 208 processes provide an appropriate model for section 255 enforcement. Hence, in the Report and Order, we decided to abandon the 5-day ''fast track'' proposal and to adopt rules modeled after our section 208 complaint rules, thus reducing the implicit burden placed on both consumers and industry alike.

145. Under the procedures adopted by the Report and Order, consumer complaints filed pursuant to section 255 will be handled through an informal complaint process where the staff refers complaints to the manufacturers or service providers involved. The focus at this stage will be on addressing the accessibility needs of the complainant. Because the nature or complexity of certain accessibility disputes may not be susceptible to informal resolution by the disputing parties, complainants have the option of seeking the formal adjudication of a problem or dispute with a manufacturer or service provider at any time pursuant to our existing section 208 complaint rules.

146. As outlined in the Report and Order we have declined to promulgate specific rules governing the design process, although certain of the Access Board Guidelines that we have may require manufacturers to include persons with disabilities in any group testing performed during the design process.

147. We believe we have reduced regulatory burdens wherever possible. For burdens imposed by achieving accessibility, the structure of the statute inherently acknowledges varying degrees of economic impact. The ''readily achievable'' standard is

proportional, not absolute, and adjusts the burden of providing accessible features commensurate with the resources of the covered entity. For burdens associated with enforcement, we anticipate that the informal complaint process will significantly reduce the number of complaints, thus minimizing the burden on all covered entities of providing a legal defense. Moreover, the range of choices for resolving complaints is designed to reduce costs to the opposing parties. Encouraging the use of streamlined, informal complaints or alternative dispute resolution primarily benefits individual plaintiffs who may be persons with disabilities with limited financial resources, but should also enable covered entities to defend themselves at a lower cost.

148. The Commission will forward a copy of the Report and Order, including this FRFA, in a report to be sent to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996. In addition, the Commission will forward a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy for the Small Business Administration. A copy of the Report and Order and FRFA (or summaries thereof) will also be published in the **Federal Register**.

VII. Paperwork Reduction Act

149. The decision herein has been analyzed with respect to the Paperwork Reduction Act of 1995, Public Law 104–13, and the Office of Management and Budget (''OMB'') has approved some of its information collection requirements in OMB No. 3060–0833, dated August 4, 1998. This Order also contains some modified information collection. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public to comment on the information collection contained in the Order as required by the Paperwork Reduction Act of 1995, public law 104–13. Public and agency comments are due December 20, 1999. Comments should address: (a) Whether the modified collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and the clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

VIII. Ordering Clauses

150. The authority contained in sections 1, 2, 4, 201(b), 208, 251(a)(2), 255, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154, 201(b), 208, 251(a)(2), 255, 303(r), this Order IS ADOPTED.

151. *It is ordered* That 47 C.F.R. part 1 is revised, and parts 6 and 7 are added as set forth below.

152. *It is ordered* That the Commission's Office of Public affairs SHALL SEND a copy of this Report and Order, including the FRFA, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act 5 U.S.C. 601, *et seq.*

153. The Report and Order IS ADOPTED, and the requirements contained herein will become effective January 28, 2000, expect for §§ 6.18 and 7.18, which will become effective upon approval of OMB of the modified information requirements contained herein. Notice of that approval will be published in the **Federal Register**.

List of Subjects in 47 CFR Part 1, 6 and 7

Communications equipment, Individuals with disabilities, Telecommunications.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

Rule Changes

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR chapter I as set forth below:

PART 1—PRACTICE AND PROCEDURE

1. The authority citation for part 1 is revised to read as follows:

Authority: 47 U.S.C. 1, 154(i), 154 (j), 208, and 255.

2. Section 1.1202 is amended by revising paragraph (d)(2) to read as follows:

§ 1.1202 Definitions.

* * * * *

(d) * * *

(2) Any person who files a complaint which shows that the complainant has served it on the subject of the complaint or which is a formal complaint under 47 U.S.C. 208 and § 1.721 or 47 U.S.C. 255 and either §§ 6.17 or 7.17 of this chapter, and the person who is the subject of such a complaint that shows service or is a formal complaint under 47 U.S.C. 208 and § 1.721 or 47 U.S.C. 255 and either §§ 6.17 or 7.17 of this chapter;

* * * * *

3. Section 1.1204 is amended by revising paragraph (b)(5) to read as follows:

§ 1.1204 Example ex parte presentations and proceedings.

* * * * *

(b) * * *

(5) An informal complaint proceeding under 47 U.S.C. 208 and § 1.717 of this chapter or 47 U.S.C. 255 and either §§ 6.17 or 7.17 of this chapter; and

* * * * *

4. Add part 6 to read as follows:

PART 6—ACCESS TO TELECOMMUNICATIONS SERVICE, TELECOMMUNICATIONS EQUIPMENT AND CUSTOMER PREMISES EQUIPMENT BY PERSONS WITH DISABILITIES

Subpart A—Scope—Who Must Comply With These Rules?

6.1 Applicability.

Subpart B—Definitions

6.3 Definitions.

Subpart C—Obligations—What Must Covered Entities Do?

6.5 General obligations.
6.7 Product design, development and evaluation.
6.9 Information pass through.
6.11 Information, documentation and training.

Subpart D—Enforcement

6.15 Generally.
6.16 Informal or formal complaints.
6.17 Informal complaints; form and content.
6.18 Procedure; designation of agents for service.
6.19 Answers to informal complaints.
6.20 Review and disposition of informal complaints.
6.21 Formal complaints, applicability of §§ 1.720 through 1.736 of this chapter.
6.22 Formal complaints based on unsatisfied informal complaints.
6.23 Actions by the Commission on its own motion.

Authority: 47 U.S.C. 154(i), 154(j), 208, 255.

Subpart A—Scope—Who Must Comply With These Rules?

§ 6.1 Applicability.

The rules in this part apply to:

(a) Any provider of telecommunications service;

(b) Any manufacturer of telecommunications equipment or customer premises equipment; and

(c) Any telecommunications carrier.

Subpart B—Definitions

§ 6.3 Definitions.

(a) The term *accessible* shall mean that:

(1) Input, control, and mechanical functions shall be locatable, identifiable, and operable in accordance with each of the following, assessed independently:

(i) Operable without vision. Provide at least one mode that does not require user vision.

(ii) Operable with low vision and limited or no hearing. Provide at least one mode that permits operation by users with visual acuity between 20/70 and 20/200, without relying on audio output.

(iii) Operable with little or no color perception. Provide at least one mode that does not require user color perception.

(iv) Operable without hearing. Provide at least one mode that does not require user auditory perception.

(v) Operable with limited manual dexterity. Provide at least one mode that does not require user fine motor control or simultaneous actions.

(vi) Operable with limited reach and strength. Provide at least one mode that is operable with user limited reach and strength.

(vii) Operable with a Prosthetic Device. Controls shall be operable without requiring body contact or close body proximity.

(viii) Operable without time-dependent controls. Provide at least one mode that does not require a response time or allows response time to be by-passed or adjusted by the user over a wide range.

(ix) Operable without speech. Provide at least one mode that does not require user speech.

(x) Operable with limited cognitive skills. Provide at least one mode that minimizes the cognitive, memory, language, and learning skills required of the user.

(2) All information necessary to operate and use the product, including but not limited to, text, static or dynamic images, icons, labels, sounds, or incidental operating cues, comply with each of the following, assessed independently:

(i) Availability of visual information. Provide visual information through at least one mode in auditory form.

(ii) Availability of visual information for low vision users. Provide visual information through at least one mode to users with visual acuity between 20/70 and 20/200 without relying on audio.

(iii) Access to moving text. Provide moving text in at least one static presentation mode at the option of the user.

(iv) Availability of auditory information. Provide auditory information through at least one mode in visual form and, where appropriate, in tactile form.

(v) Availability of auditory information for people who are hard of hearing. Provide audio or acoustic information, including any auditory feedback tones that are important for the use of the product, through at least one mode in enhanced auditory fashion (*i.e.*, increased amplification, increased signal-to-noise ratio, or combination).

(vi) Prevention of visually-induced seizures. Visual displays and indicators shall minimize visual flicker that might induce seizures in people with photosensitive epilepsy.

(vii) Availability of audio cutoff. Where a product delivers audio output through an external speaker, provide an industry standard connector for headphones or personal listening devices (*e.g.*, phone-like handset or earcup) which cuts off the speaker(s) when used.

(viii) Non-interference with hearing technologies. Reduce interference to hearing technologies (including hearing aids, cochlear implants, and assistive listening devices) to the lowest possible level that allows a user to utilize the product.

(ix) Hearing aid coupling. Where a product delivers output by an audio transducer which is normally held up to the ear, provide a means for effective wireless coupling to hearing aids.

(b) The term *compatibility* shall mean compatible with peripheral devices and specialized customer premises equipment commonly used by individuals with disabilities to achieve accessibility to telecommunications services, and in compliance with the following provisions, as applicable:

(1) External electronic access to all information and control mechanisms. Information needed for the operation of products (including output, alerts, icons, on-line help, and documentation) shall be available in a standard electronic text format on a cross-industry standard port and all input to and control of a product shall allow for real time operation by electronic text input into a cross-industry standard external port and in cross-industry standard format. The cross-industry standard port shall not require manipulation of a connector by the user.

(2) Connection point for external audio processing devices. Products providing auditory output shall provide the auditory signal at a standard signal level through an industry standard connector.

(3) TTY connectability. Products which provide a function allowing voice communication and which do not themselves provide a TTY functionality shall provide a standard non-acoustic connection point for TTYs. It shall also be possible for the user to easily turn any microphone on and off to allow the user to intermix speech with TTY use.

(4) TTY signal compatibility. Products, including those providing voice communication functionality, shall support use of all cross-manufacturer non-proprietary standard signals used by TTYs.

(c) The term *customer premises equipment* shall mean equipment employed on the premises of a person (other than a carrier) to originate, route, or terminate telecommunications.

(d) The term *disability* shall mean a physical or mental impairment that substantially limits one or more of the major life activities of an individual; a record of such an impairment; or being regarded as having such an impairment.

(e) The term *manufacturer* shall mean an entity that makes or produces a product.

(f) The term *peripheral devices* shall mean devices employed in connection with equipment covered by this part to translate, enhance, or otherwise transform telecommunications into a form accessible to individuals with disabilities.

(g) The term *readily achievable* shall mean, in general, easily accomplishable and able to be carried out without much difficulty or expense. In determining whether an action is readily achievable, factors to be considered include:

(1) The nature and cost of the action needed;

(2) The overall financial resources of the manufacturer or service provider involved in the action (the covered entity); the number of persons employed by such manufacturer or service provider; the effect on expenses and resources, or the impact otherwise of such action upon the operations of the manufacturer or service provider;

(3) If applicable, the overall financial resources of the parent of the entity; the overall size of the business of the parent entity with respect to the number of its employees; the number, type, and location of its facilities; and

(4) If applicable, the type of operation or operations of the covered entity, including the composition, structure and functions of the workforce of such entity; and the geographic separateness, administrative or fiscal relationship of the covered entity in question to the parent entity.

(h) The term *specialized customer premises equipment* shall mean

customer premise equipment which is commonly used by individuals with disabilities to achieve access.

(i) The term *telecommunications equipment* shall mean equipment, other than customer premises equipment, used by a carrier to provide telecommunications services, and includes software integral to such equipment (including upgrades).

(j) The term *telecommunications service* shall mean the offering of telecommunications for a fee directly to the public, or to such classes of users as to be effectively available directly to the public, regardless of the facilities used.

(k) The term *usable* shall mean that individuals with disabilities have access to the full functionality and documentation for the product, including instructions, product information (including accessible feature information), documentation, bills and technical support which is provided to individuals without disabilities.

Subpart C—Obligations—What Must Covered Entities Do?

§ 6.5 General obligations.

(a) *Obligation of Manufacturers.* (1) A manufacturer of telecommunications equipment or customer premises equipment shall ensure that the equipment is designed, developed and fabricated so that the telecommunications functions of the equipment are accessible to and usable by individuals with disabilities, if readily achievable.

(2) Whenever the requirements of paragraph (a)(1) of this section are not readily achievable, the manufacturer shall ensure that the equipment is compatible with existing peripheral devices or specialized customer premises equipment commonly used by individuals with disabilities to achieve access, if readily achievable.

(b) *Obligation of Service Providers.* (1) A provider of a telecommunications service shall ensure that the service is accessible to and usable by individuals with disabilities, if readily achievable.

(2) Whenever the requirements of paragraph (b)(1) of this section are not readily achievable, the service provider shall ensure that the service is compatible with existing peripheral devices or specialized customer premises equipment commonly used by individuals with disabilities to achieve access, if readily achievable.

(c) *Obligation of Telecommunications Carriers.* Each telecommunications carrier must not install network features, functions, or capabilities that do not comply with the guidelines and standards established pursuant to this part or part 7 of this chapter.

§ 6.7 Product design, development, and evaluation.

(a) Manufacturers and service providers shall evaluate the accessibility, usability, and compatibility of equipment and services covered by this part and shall incorporate such evaluation throughout product design, development, and fabrication, as early and consistently as possible. Manufacturers and service providers shall identify barriers to accessibility and usability as part of such a product design and development process.

(b) In developing such a process, manufacturers and service providers shall consider the following factors, as the manufacturer deems appropriate:

(1) Where market research is undertaken, including individuals with disabilities in target populations of such research;

(2) Where product design, testing, pilot demonstrations, and product trials are conducted, including individuals with disabilities in such activities;

(3) Working cooperatively with appropriate disability-related organizations; and

(4) Making reasonable efforts to validate any unproven access solutions through testing with individuals with disabilities or with appropriate disability-related organizations that have established expertise with individuals with disabilities.

§ 6.9 Information pass through.

Telecommunications equipment and customer premises equipment shall pass through cross-manufacturer, non-proprietary, industry-standard codes, translation protocols, formats or other information necessary to provide telecommunications in an accessible format, if readily achievable. In particular, signal compression technologies shall not remove information needed for access or shall restore it upon decompression.

§ 6.11 Information, documentation, and training.

(a) Manufacturers and service providers shall ensure access to information and documentation it provides to its customers, if readily achievable. Such information and documentation includes user guides, bills, installation guides for end-user installable devices, and product support communications, regarding both the product in general and the accessibility features of the product. Manufacturers shall take such other readily achievable steps as necessary including:

(1) Providing a description of the accessibility and compatibility features of the product upon request, including, as needed, in alternate formats or alternate modes at no additional charge;

(2) Providing end-user product documentation in alternate formats or alternate modes upon request at no additional charge; and

(3) Ensuring usable customer support and technical support in the call centers and service centers which support their products at no additional charge.

(b) Manufacturers and service providers shall include in general product information the contact method for obtaining the information required by paragraph (a) of this section.

(c) In developing, or incorporating existing training programs, manufacturers and service providers, shall consider the following topics:

(1) Accessibility requirements of individuals with disabilities;

(2) Means of communicating with individuals with disabilities;

(3) Commonly used adaptive technology used with the manufacturer's products;

(4) Designing for accessibility; and

(5) Solutions for accessibility and compatibility.

Subpart D—Enforcement

§ 6.15 Generally.

(a) All manufacturers of telecommunications equipment or customer premise equipment (CPE) and all providers of telecommunications services, as defined under this subpart, are subject to the enforcement provisions specified in the Act and the Commission's rules.

(b) For purposes of §§ 6.15 through 6.23, the term ''manufacturers'' shall denote manufacturers of telecommunications equipment or CPE and the term ''providers'' shall denote providers of telecommunications services.

§ 6.16 Informal or formal complaints.

Complaints against manufacturers or providers, as defined under this subpart, for alleged violations of this subpart may be either informal or formal.

§ 6.17 Informal complaints; form and content.

(a) An informal complaint alleging a violation of section 255 of the Act or this subpart may be transmitted to the Commission by any reasonable means, *e.g.*, letter, facsimile transmission, telephone (voice/TRS/TTY), Internet e-mail, ASCII text, audio-cassette recording, and braille.

(b) An informal complaint shall include:

(1) The name and address of the complainant;

(2) The name and address of the manufacturer or provider against whom the complaint is made;

(3) A full description of the telecommunications equipment or CPE and/or the telecommunications service about which the complaint is made;

(4) The date or dates on which the complainant either purchased, acquired or used, or attempted to purchase, acquire or use the telecommunications equipment, CPE or telecommunications service about which the complaint is being made;

(5) A complete statement of the facts, including documentation where available, supporting the complainant's allegation that: such telecommunications service, or such telecommunications equipment or CPE, is not accessible to, or usable by, a person with a particular disability or persons with disabilities within the meaning of this subpart and section 255 of the Act; or that the defendant has otherwise failed to comply with the requirements of this subpart;

(6) The specific relief or satisfaction sought by the complainant, and

(7) The complainant's preferred format or method of response to the complaint by the Commission and defendant (*e.g.*, letter, facsimile transmission, telephone (voice/TRS/TTY), Internet e-mail, ASCII text, audio-cassette recording, braille; or some other method that will best accommodate the complainant's disability)

§ 6.18 Procedure; designation of agents for service.

(a) The Commission shall promptly forward any informal complaint meeting the requirements of § 6.17 to each manufacturer and provider named in or determined by the staff to be implicated by the complaint. Such manufacturer(s) or provider(s) shall be called on to satisfy or answer the complaint within the time specified by the Commission.

(b) To ensure prompt and effective service of informal and formal complaints filed under this subpart, every manufacturer and provider subject to the requirements of section 255 of the Act and this subpart, shall designate an agent, and may designate additional agents if it so chooses, upon whom service may be made of all notices, inquiries, orders, decisions, and other pronouncements of the Commission in any matter before the Commission. Such designation shall include, for both the manufacturer or the provider, a name or department designation, business address, telephone number, and, if available TTY number, facsimile number, and Internet e-mail address.

§ 6.19 Answers to informal complaints.

Any manufacturer or provider to whom an informal complaint is directed by the Commission under this subpart shall file an answer within the time specified by the Commission. The answer shall:

(a) Be prepared or formatted in the manner requested by the complainant pursuant to § 6.17, unless otherwise permitted by the Commission for good cause shown;

(b) Describe any actions that the defendant has taken or proposes to take to satisfy the complaint;

(c) Advise the complainant and the Commission of the nature of the defense(s) claimed by the defendant;

(d) Respond specifically to all material allegations of the complaint; and

(e) Provide any other information or materials specified by the Commission as relevant to its consideration of the complaint.

§ 6.20 Review and disposition of informal complaints.

(a) Where it appears from the defendant's answer, or from other communications with the parties, that an informal complaint has been satisfied, the Commission may, in its discretion, consider the informal complaint closed, without response to the complainant or defendant. In all other cases, the Commission shall inform the parties of its review and disposition of a complaint filed under this subpart. Where practicable, this information, the nature of which is specified in paragraphs (b) through (d) of this section, shall be transmitted to the complainant and defendant in the manner requested by the complainant, (*e.g.*, letter, facsimile transmission, telephone (voice/TRS/TTY), Internet e-mail, ASCII text, audio-cassette recording, or braille).

(b) In the event the Commission determines, based on a review of the information provided in the informal complaint and the defendant's answer thereto, that no further action is required by the Commission with respect to the allegations contained in the informal complaint, the informal complaint shall be closed and the complainant and defendant shall be duly informed of the reasons therefor. A complainant unsatisfied with the defendant's response to the informal complaint and the staff decision to terminate action on the informal complaint may file a formal complaint with the Commission, as specified in § 6.22.

(c) In the event the Commission determines, based on a review of the information presented in the informal complaint and the defendant's answer thereto, that a material and substantial question remains as to the defendant's compliance with the requirements of this subpart, the Commission may conduct such further investigation or such further proceedings as may be necessary to determine the defendant's compliance with the requirements of this subpart and to determine what, if any, remedial actions and/or sanctions are warranted.

(d) In the event that the Commission determines, based on a review of the information presented in the informal complaint and the defendant's answer thereto, that the defendant has failed to comply with or is presently not in compliance with the requirements of this subpart, the Commission may order or prescribe such remedial actions and/or sanctions as are authorized under the Act and the Commission's rules and which are deemed by the Commission to be appropriate under the facts and circumstances of the case.

§ 6.21 Formal complaints, applicability of §§ 1.720 through 1.736 of this chapter.

Formal complaints against a manufacturer or provider, as defined under this subpart, may be filed in the form and in the manner prescribed under §§ 1.720 through 1.736 of this chapter. Commission staff may grant waivers of, or exceptions to, particular requirements under §§ 1.720 through 1.736 of this chapter for good cause shown; provided, however, that such waiver authority may not be exercised in a manner that relieves, or has the effect of relieving, a complainant of the obligation under §§ 1.720 and 1.728 of this chapter to allege facts which, if true, are sufficient to constitute a violation or violations of section 255 of the Act or this subpart.

§ 6.22 Formal complaints based on unsatisfied informal complaints.

A formal complaint filing based on an unsatisfied informal complaint filed pursuant to § 4.16 of this chapter shall be deemed to relate back to the filing date of the informal complaint if it is filed within ninety days from the date that the Commission notifies the complainant of its disposition of the informal complaint and based on the same operative facts as those alleged in the informal complaint.

§ 6.23 Actions by the Commission on its own motion.

The Commission may on its own motion conduct such inquiries and hold such proceedings as it may deem necessary to enforce the requirements of this subpart and section 255 of the Communications Act. The procedures to be followed by the Commission shall, unless specifically prescribed in the Act and the Commission's rules, be such as in the opinion of the Commission will best serve the purposes of such inquiries and proceedings.

2. Add part 7 to read as follows:

PART 7—ACCESS TO VOICEMAIL AND INTERACTIVE MENU SERVICES AND EQUIPMENT BY PEOPLE WITH DISABILITIES

Subpart A—Scope—Who Must Comply With These Rules?

Sec.
7.1 Who must comply with these rules?

Subpart B—Definitions

7.3 Definitions.

Subpart C—Obligations—What Must Covered Entities Do?

7.5 General obligations.
7.7 Product design, development and evaluation.
7.9 Information pass through.
7.11 Information, documentation and training.

Subpart D—Enforcement

7.15 Generally.
7.16 Informal or formal complaints.
7.17 Informal complaints; form and content.
7.18 Procedure; designation of agents for service.
7.19 Answers to informal complaints.
7.20 Review and disposition of informal complaints.
7.21 Formal complaints, applicability of §§ 1.720 through 1.736 of this chapter.
7.22 Formal complaints based on unsatisfied informal complaints.
7.23 Actions by the Commission on its own motion.

Authority: 47 U.S.C. 1, 154(i), 154(j) 208, and 255.

Subpart A—Scope—Who Must Comply With These Rules?

§ 7.1 Who must comply with these rules?

The rules in this part apply to:

(a) Any provider of voicemail or interactive menu service;

(b) Any manufacturer of telecommunications equipment or customer premises equipment which performs a voicemail or interactive menu function.

Subpart B—Definitions

§ 7.3 Definitions.

(a) The term *accessible* shall mean that:

(1) Input, control, and mechanical functions shall be locatable, identifiable, and operable in accordance with each of the following, assessed independently:

(i) Operable without vision. Provide at least one mode that does not require user vision.

(ii) Operable with low vision and limited or no hearing. Provide at least one mode that permits operation by users with visual acuity between 20/70 and 20/200, without relying on audio output.

(iii) Operable with little or no color perception. Provide at least one mode that does not require user color perception.

(iv) Operable without hearing. Provide at least one mode that does not require user auditory perception.

(v) Operable with limited manual dexterity. Provide at least one mode that does not require user fine motor control or simultaneous actions.

(vi) Operable with limited reach and strength. Provide at least one mode that is operable with user limited reach and strength.

(vii) Operable with a Prosthetic Device. Controls shall be operable without requiring body contact or close body proximity.

(viii) Operable without time-dependent controls. Provide at least one mode that does not require a response time or allows a response to be by-passed or adjusted by the user over a wide range.

(ix) Operable without speech. Provide at least one mode that does not require user speech.

(x) Operable with limited cognitive skills. Provide at least one mode that minimizes the cognitive, memory, language, and learning skills required of the user.

(2) All information necessary to operate and use the product, including but not limited to, text, static or dynamic images, icons, labels, sounds, or incidental operating cues, comply with each of the following, assessed independently:

(i) Availability of visual information. Provide visual information through at least one mode in auditory form.

(ii) Availability of visual information for low vision users. Provide visual information through at least one mode to users with visual acuity between 20/70 and 20/200 without relying on audio.

(iii) Access to moving text. Provide moving text in at least one static presentation mode at the option of the user.

(iv) Availability of auditory information. Provide auditory information through at least one mode in visual form and, where appropriate, in tactile form.

(v) Availability of auditory information for people who are hard of hearing. Provide audio or acoustic information, including any auditory feedback tones that are important for the use of the product, through at least one mode in enhanced auditory fashion (*i.e.*, increased amplification, increased signal-to-noise ratio, or combination).

(vi) Prevention of visually-induced seizures. Visual displays and indicators shall minimize visual flicker that might induce seizures in people with photosensitive epilepsy.

(vii) Availability of audio cutoff. Where a product delivers audio output through an external speaker, provide an industry standard connector for headphones or personal listening devices (*e.g.*, phone-like handset or earcup) which cuts off the speaker(s) when used.

(viii) Non-interference with hearing technologies. Reduce interference to hearing technologies (including hearing aids, cochlear implants, and assistive listening devices) to the lowest possible level that allows a user to utilize the product.

(ix) Hearing aid coupling. Where a product delivers output by an audio transducer which is normally held up to the ear, provide a means for effective wireless coupling to hearing aids.

(b) The term *compatibility* shall mean compatible with peripheral devices and specialized customer premises equipment commonly used by individuals with disabilities to achieve accessibility to voicemail and interactive menus, and in compliance with the following provisions, as applicable:

(1) External electronic access to all information and control mechanisms. Information needed for the operation of products (including output, alerts, icons, on-line help, and documentation) shall be available in a standard electronic text format on a cross-industry standard port and all input to and control of a product shall allow for real time operation by electronic text input into a cross-industry standard external port and in cross-industry standard format. The cross-industry standard port shall not require manipulation of a connector by the user.

(2) Connection point for external audio processing devices. Products providing auditory output shall provide the auditory signal at a standard signal level through an industry standard connector.

(3) TTY connectability. Products which provide a function allowing voice communication and which do not themselves provide a TTY functionality shall provide a standard non-acoustic connection point for TTYs. It shall also be possible for the user to easily turn any microphone on and off to allow the user to intermix speech with TTY use.

(4) TTY signal compatibility. Products, including those providing voice communication functionality, shall support use of all cross-manufacturer non-proprietary standard signals used by TTYs.

(c) The term *customer premises equipment* shall mean equipment employed on the premises of a person (other than a carrier) to originate, route, or terminate telecommunications.

(d) The term *disability* shall mean a physical or mental impairment that substantially limits one or more of the major life activities of an individual; a record of such an impairment; or being regarded as having such an impairment.

(e) The term *interactive menu* shall mean a feature that allows a service provider or operator of CPE to transmit information to a caller in visual and/or audible format for the purpose of management, control, or operations of a telecommunications system or service; and/or to request information from the caller in visual and/or audible format for the purpose of management, control, or operations of a telecommunications system or service; and/or to receive information from the caller in visual and/or audible format in response to a request, for the purpose of management, control, or operations of a telecommunications system or service. This feature, however, does not include the capability for generating, acquiring, storing, transforming, processing, retrieving, utilizing, or making available information via telecommunications for any purpose other than management, control, or operations of a telecommunications system or service.

(f) The term *manufacturer* shall mean an entity that makes or produces a product.

(g) The term *peripheral devices* shall mean devices employed in connection with equipment covered by this part to translate, enhance, or otherwise transform telecommunications into a form accessible to individuals with disabilities.

(h) The term *readily achievable* shall mean, in general, easily accomplishable and able to be carried out without much difficulty or expense. In determining whether an action is readily achievable, factors to be considered include:

(1) The nature and cost of the action needed;

(2) The overall financial resources of the manufacturer or service provider involved in the action (the covered entity); the number of persons employed by such manufacturer or service provider; the effect on expenses and resources, or the impact otherwise of such action upon the operations of the manufacturer or service provider;

(3) If applicable, the overall financial resources of the parent of the covered entity; the overall size of the business of the parent of the covered entity with respect to the number of its employees; the number, type, and location of its facilities; and

(4) If applicable, the type of operation or operations of the covered entity, including the composition, structure and functions of the workforce of such entity; and the geographic separateness, administrative or fiscal relationship of covered entity in question to the parent entity.

(i) The term *specialized customer premises equipment* shall mean customer premise equipment which is commonly used by individuals with disabilities to achieve access.

(j) The term *telecommunications equipment* shall mean equipment, other than customer premises equipment, used by a carrier to provide telecommunications services, and includes software integral to such equipment (including upgrades).

(k) The term *telecommunications service* shall mean the offering of telecommunications for a fee directly to the public, or to such classes of users as to be effectively available directly to the public, regardless of the facilities used.

(l) The term *usable* shall mean that individuals with disabilities have access to the full functionality and documentation for the product, including instructions, product information (including accessible feature information), documentation, bills and technical support which is provided to individuals without disabilities.

(m) The term *Voicemail* shall mean the capability of answering calls and recording incoming messages when a line is busy or does not answer within a pre-specified amount of time or number of rings; receiving those messages at a later time; and may also include the ability to determine the sender and time of transmission without hearing the entire message; the ability to forward the message to another voice massaging customer, with and/or without an appended new message; the ability for the sender to confirm receipt of a message; the ability to send, receive, and/or store facsimile messages; and possibly other features.

Subpart C—Obligations—What Must Covered Entities Do?

§ 7.5 General Obligations.

(a) Obligation of Manufacturers. (1) A manufacturer of telecommunications equipment or customer premises equipment covered by this part shall ensure that the equipment is designed, developed and fabricated so that the voicemail and interactive menu functions are accessible to and usable by individuals with disabilities, if readily achievable;

(2) Whenever the requirements of paragraph (a)(1) of this section are not readily achievable, the manufacturer shall ensure that the equipment is compatible with existing peripheral devices or specialized customer premises equipment commonly used by individuals with disabilities to achieve access, if readily achievable.

(b) Obligation of Service Providers. (1) A provider of voicemail or interactive menu shall ensure that the service is accessible to and usable by individuals with disabilities, if readily achievable.

(2) Whenever the requirements of paragraph (a)(1) of this section are not readily achievable, the service provider shall ensure that the service is compatible with existing peripheral devices or specialized customer premises equipment commonly used by individuals with disabilities to achieve access, if readily achievable.

§ 7.7 Product design, development, and evaluation.

(a) Manufacturers and service providers shall evaluate the accessibility, usability, and compatibility of equipment and services covered by this part and shall incorporate such evaluation throughout product design, development, and fabrication, as early and consistently as possible. Manufacturers and service providers shall identify barriers to accessibility and usability as part of such a product design and development process.

(b) In developing such a process, manufacturers and service providers shall consider the following factors, as the manufacturer deems appropriate:

(1) Where market research is undertaken, including individuals with disabilities in target populations of such research;

(2) Where product design, testing, pilot demonstrations, and product trials are conducted, including individuals with disabilities in such activities;

(3) Working cooperatively with appropriate disability-related organizations; and

(4) Making reasonable efforts to validate any unproven access solutions through testing with individuals with disabilities or with appropriate disability-related organizations that have established expertise with individuals with disabilities.

§ 7.9 Information pass through.

Telecommunications equipment and customer premises equipment shall pass through cross-manufacturer, non-proprietary, industry-standard codes, translation protocols, formats or other information necessary to provide telecommunications in an accessible format, if readily achievable. In particular, signal compression technologies shall not remove information needed for access or shall restore it upon decompression.

§ 7.11 Information, documentation, and training.

(a) Manufacturers and service providers shall ensure access to information and documentation it provides to its customers, if readily achievable. Such information and documentation includes user guides, bills, installation guides for end-user installable devices, and product support communications, regarding both the product in general and the accessibility features of the product. Manufacturers shall take such other readily achievable steps as necessary including:

(1) Providing a description of the accessibility and compatibility features of the product upon request, including, as needed, in alternate formats or alternate modes at no additional charge;

(2) Providing end-user product documentation in alternate formats or alternate modes upon request at no additional charge; and

(3) Ensuring usable customer support and technical support in the call centers and service centers which support their products at no additional charge.

(b) Manufacturers and service providers shall include in general product information the contact method for obtaining the information required by paragraph (a) of this section.

(c) In developing, or incorporating existing training programs, manufacturers and service providers shall consider the following topics:

(1) Accessibility requirements of individuals with disabilities;

(2) Means of communicating with individuals with disabilities;

(3) Commonly used adaptive technology used with the manufacturer's products;

(4) Designing for accessibility; and

(5) Solutions for accessibility and compatibility.

Subpart D—Enforcement

§ 7.15 Generally.

(a) For purposes of §§ 7.15–7.23 of this subpart, the term ''manufacturers'' shall denote any manufacturer of telecommunications equipment or customer premises equipment which performs a voicemail or interactive menu function.

(b) All manufacturers of telecommunications equipment or customer premise equipment (CPE) and all providers of voicemail and interactive menu services, as defined under this subpart, are subject to the enforcement provisions specified in the Act and the Commission's rules.

(c) The term ''providers'' shall denote any provider of voicemail or interactive menu service.

§ 7.16 Informal or formal complaints.

Complaints against manufacturers or providers, as defined under this subpart, for alleged violations of this subpart may be either informal or formal.

§ 7.17 Informal complaints; form and content.

(a) An informal complaint alleging a violation of section 255 of the Act or this subpart may be transmitted to the Commission by any reasonable means, *e.g.*, letter, facsimile transmission, telephone (voice/TRS/TTY), Internet e-mail, ASCII text, Internet e-mail, audio-cassette recording, and braille.

(b) An informal complaint shall include:

(1) The name and address of the complainant;

(2) The name and address of the manufacturer or provider against whom the complaint is made;

(3) A full description of the telecommunications equipment or CPE and/or the telecommunications service about which the complaint is made;

(4) The date or dates on which the complainant either purchased, acquired or used, or attempted to purchase, acquire or use the telecommunications equipment, CPE or telecommunications service about which the complaint is being made;

(5) A complete statement of the facts, including documentation where available, supporting the complainant's allegation that: such telecommunications service, or such telecommunications equipment or CPE, is not accessible to, or usable by, a person with a particular disability or persons with disabilities within the meaning of this subpart and section 255 of the Act; or that the defendant has otherwise failed to comply with the requirements of this subpart.

(6) The specific relief or satisfaction sought by the complainant, and

(7) The complainant's preferred format or method of response to the complaint by the Commission and defendant (*e.g.*, letter, facsimile transmission, telephone (voice/TRS/TTY), Internet e-mail, ASCII text, audio-cassette recording, braille; or some other method that will best accommodate the complainant's disability).

§ 7.18 Procedure; designation of agents for service.

(a) The Commission shall promptly forward any informal complaint meeting the requirements of § 7.17 to each manufacturer and provider named in or determined by the staff to be implicated by the complaint. Such manufacturer(s) or provider(s) shall be called on to satisfy or answer the complaint within the time specified by the Commission.

(b) To ensure prompt and effective service of informal and formal complaints filed under this subpart, every manufacturer and provider subject to the requirements of section 255 of the Act and this subpart, shall designate an agent, and may designate additional agents if it so chooses, upon whom service may be made of all notices, inquiries, orders, decisions, and other pronouncements of the Commission in any matter before the Commission. Such designation shall include, for both the manufacturer or the provider, a name or department designation, business address, telephone number, and, if available TTY number, facsimile number, and Internet e-mail address.

§ 7.19 Answers to informal complaints.

Any manufacturer or provider to whom an informal complaint is directed by the Commission under this subpart shall file an answer within the time specified by the Commission. The answer shall:

(a) Be prepared or formatted in the manner requested by the complainant pursuant to § 7.17, unless otherwise permitted by the Commission for good cause shown;

(b) Describe any actions that the defendant has taken or proposes to take to satisfy the complaint;

(c) Advise the complainant and the Commission of the nature of the defense(s) claimed by the defendant;

(d) Respond specifically to all material allegations of the complaint; and

(e) Provide any other information or materials specified by the Commission as relevant to its consideration of the complaint.

§ 7.20 Review and disposition of informal complaints.

(a) Where it appears from the defendant's answer, or from other communications with the parties, that an informal complaint has been satisfied, the Commission may, in its discretion, consider the informal complaint closed, without response to the complainant or defendant. In all other cases, the Commission shall inform the parties of its review and disposition of a complaint filed under this subpart. Where practicable, this information, the nature of which is specified in paragraphs (b) through (d) of this section, shall be transmitted to the complainant and defendant in the manner requested by the complainant, (*e.g.*, letter, facsimile transmission, telephone (voice/TRS/TTY), Internet e-mail, ASCII text, audio-cassette recording, or braille).

(b) In the event the Commission determines, based on a review of the information provided in the informal complaint and the defendant's answer thereto, that no further action is required by the Commission with respect to the allegations contained in the informal complaint, the informal complaint shall be closed and the complainant and defendant shall be duly informed of the reasons therefor. A complainant unsatisfied with the defendant's response to the informal complaint and the staff decision to terminate action on the informal complaint may file a formal complaint with the Commission, as specified in § 7.22 of this subpart.

(c) In the event the Commission determines, based on a review of the information presented in the informal complaint and the defendant's answer thereto, that a material and substantial question remains as to the defendant's compliance with the requirements of this subpart, the Commission may conduct such further investigation or such further proceedings as may be necessary to determine the defendant's compliance with the requirements of this subpart and to determine what, if any, remedial actions and/or sanctions are warranted.

(d) In the event that the Commission determines, based on a review of the information presented in the informal complaint and the defendant's answer thereto, that the defendant has failed to comply with or is presently not in compliance with the requirements of this subpart, the Commission may order or prescribe such remedial actions and/or sanctions as are authorized under the Act and the Commission's rules and which are deemed by the Commission to be appropriate under the facts and circumstances of the case.

§ 7.21 Formal complaints, applicability of §§ 1.720 through 1.736 of this chapter.

Formal complaints against a manufacturer or provider, as defined under this subpart, may be filed in the form and in the manner prescribed under §§ 1.720 through 1.736 of this chapter. Commission staff may grant waivers of, or exceptions to, particular requirements under §§ 1.720 through 1.736 for good cause shown; provided, however, that such waiver authority may not be exercised in a manner that relieves, or has the effect of relieving, a complainant of the obligation under §§ 1.720 and 1.728 of this chapter to allege facts which, if true, are sufficient to constitute a violation or violations of section 255 of the Act or this chapter.

§ 7.22 Formal complaints based on unsatisfied informal complaints.

A formal complaint filing based on an unsatisfied informal complaint filed pursuant to § 4.16 of this chapter shall be deemed to relate back to the filing date of the informal complaint if it is filed within ninety days from the date that the Commission notifies the complainant of its disposition of the informal complaint and based on the same operative facts as those alleged in the informal complaint.

§ 7.23 Actions by the Commission on its own motion.

The Commission may on its own motion conduct such inquiries and hold such proceedings as it may deem necessary to enforce the requirements of this part and Section 255 of the Communications Act. The procedures to be followed by the Commission shall, unless specifically prescribed in the Act and the Commission's rules, be such as in the opinion of the Commission will best serve the purposes of such inquiries and proceedings.

[FR Doc. 99–30091 Filed 11–18–99; 8:45 am]
BILLING CODE 6712–01–U

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 99–2453; MM Docket No. 90–189; RM–6904; RM–7114; RM–7186; RM–7415; RM–7298]

Radio Broadcasting Services; Farmington, Grass Valley, Jackson, CA

AGENCY: Federal Communications Commission.

ACTION: Final rule, petition for reconsideration.

SUMMARY: This document grants a Petition for Reconsideration filed by Gold Country Communications, Inc. directed to the *First Report and Order* in this proceeding. *See* 61 FR 42190, published August 14, 1996. Specifically, this document sets aside the upgrade of Station KNCO, Grass Valley, California, to Channel 232B1, the allotment of Channel 232A to Farmington, California, and the modification of the license of Station KNGT, Jackson, California, to Channel 259A. As a result of these actions, this document upgrades Station KNGT, Jackson, California, to Channel 232B1. To accommodate this upgrade, this document also modifies the license of Station KNCO, Grass Valley, California, to Channel 231A. The reference coordinates for Channel 232B1 at Jackson, California, are 38–24–44 and 120–35–32. The reference coordinates for Channel 231A at Grass Valley, California, are 39–14–44 and 120–57–52. With this action, the proceeding is terminated.

EFFECTIVE DATE: December 23, 1999.

FOR FURTHER INFORMATION CONTACT: Robert Hayne, Mass Media Bureau, (202) 418–2177.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Memorandum Opinion and Order* in MM Docket No. 90–189, adopted October 27, 1999, and released November 5, 1999. The full text of this decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW, Washington, D.C. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, D.C. 20036.

List of Subjects in 47 CFR Part 73

Radio Broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 232A at Farmington.

3. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 232B1 and adding Channel 231A at Grass Valley.

4. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 259A and adding Channel 232B1 at Jackson.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–30171 Filed 11–18–99; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 99040113–01; I.D. 093099B]

Fisheries off West Coast States and in the Western Pacific; West Coast Salmon Fisheries; Commercial Reopening from Cape Flattery to Leadbetter Point, WA

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Reopening; request for comments.

SUMMARY: NMFS announces that the commercial salmon fishery in the area between Cape Alava to Leadbetter Point, WA for all salmon except chinook reopened on September 22, 1999, with the suspension of certain gear restrictions and the coho trip limit. The fishery closed as scheduled on September 30, 1999, and will not reopen. There were 12,027 coho remaining in the quota when the fishery opened. This action was necessary to conform to the 1999 management measures and is intended to ensure conservation of chinook salmon.

DATES: Reopening the commercial salmon fishery effective 0001 hours local time (l.t.), September 22, 1999, from the area between Cape Alava to Leadbetter Point, WA. Comments will be accepted through December 6, 1999.

ADDRESSES: Comments may be mailed to William Stelle, Jr., Regional Administrator, Northwest Region, NMFS, NOAA, 7600 Sand Point Way NE., Bldg. 1, Seattle, WA 98115-0070. Information relevant to this document is available for public review during business hours at the Office of the Regional Administrator, Northwest Region, NMFS.

FOR FURTHER INFORMATION CONTACT: William Robinson, 206-526-6140.

SUPPLEMENTARY INFORMATION:

Background

In the 1999 management measures for ocean salmon fisheries (64 FR 24078, May 5, 1999), NMFS announced that the commercial fishery for all salmon from Cape Flattery (48°23'00'' N. lat.) to Cape Alava (48°10'00'' N. lat.) West of 125°05'00'' W. long. and Cape Alava to Leadbetter Point, WA, would open July 10, 1999, through the earliest of September 30, 1999, or attainment of the overall chinook quota (preseason 4,500 chinook guideline) or 20,000 coho quota. NMFS also made several other earlier inseason adjustments to this fishery which can be found in the **Federal Register** at [64 FR 42856, August 6, 1999], [64 FR October 18, 1999], and [64 FR 62127, November 16, 1999].

Salmon Inseason Actions

On September 20, 1999, the Regional Administrator consulted with representatives of the Pacific Fishery Management Council (Council), the Washington Department of Fish and Wildlife (WDFD), and the Oregon Department of Fish and Wildlife (ODFW) to discuss the status of catch in the commercial salmon fisheries north of Cape Falcon. During the recent 9-day opener for all salmon except chinook, from September 5, 1999, until September 13, 1999, only 337 coho were landed. With a landed catch so low, primarily caused by rough weather conditions and low fishing effort, the chinook hooking mortality impacts were also low. Therefore, a majority of the 770 chinook previously set aside to compensate for mortalities related to chinook hooked and released during the 9-day commercial opener targeting coho still remained. The States, therefore, recommended that the fishery reopen on September 22, 1999, and close as scheduled on September 30, 1999, with the continued suspension of certain gear restrictions (no more than 4 spreads per line; gear restricted to plugs 6 in (15.2 cm) or longer; flashers without hooks may be used if installed below the second spread from the top and will not be counted as a spread; and no more than one flasher per line), and the coho trip limit (where each vessel may possess, land and deliver no more than 100 coho per open period). As recommended, NMFS reopened the commercial salmon fishery in the area between Cape Alava to Leadbetter Point, WA, for all salmon except chinook on September 22, 1999, through the end of the season on September 30, 1999, with the continued suspension of certain gear restrictions and also the suspension of the coho trip limit.

Modification of fishing seasons is authorized by regulations at 50 CFR 660.409(b)(1). All other restrictions applicable to this fishery remained in effect as announced in the annual management measures.

In making these decisions, the Regional Administrator consulted with representatives of the Council, WDFW, and ODFW. The States of Washington and Oregon will manage the commercial fisheries in State waters adjacent to this area of the EEZ in accordance with this Federal action. As provided by the inseason notification procedures of 50 CFR 660.411, actual notification to fishermen of this action was given prior the effective date by telephone hotline numbers 206-526-6667 and 800-662-9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF-FM and 2182 kHz. Because of the need for immediate action to make inseason adjustments to allow harvest, NMFS has determined that good cause exists for this action to be issued without affording a prior opportunity for public comment. This action does not apply to other fisheries that may be operating in other areas.

Classification

This action is authorized by 50 CFR 660.409 and 660.411 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 8, 1999.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 99–30271 Filed 11-18-99; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 990304063–9063–01; I.D. 111299B]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Using Trawl Gear in the Bering Sea and Aleutian Islands.

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Modification of a closure.

SUMMARY: NMFS is opening directed fishing for Pacific cod by vessels using

trawl gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to fully utilize the 1999 halibut bycatch mortality allowance specified for the trawl Pacific cod fishery.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), November 16, 1999, until 2400 hrs. A.l.t., December 31, 1999, or until NMFS publishes further notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Andrew Smoker, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The Final 1999 Harvest Specifications of Groundfish (64 FR 12103, March 11, 1999) established the halibut bycatch mortality allowance specified for the BSAI trawl Pacific cod fishery, which is defined at § 679.21(e)(3)(iv)(E), as 1,473 metric tons (mt).

On October 18, 1999, the fishery for Pacific cod by vessels using trawl gear in the BSAI was closed to directed fishing under § 679.21(e)(7)(v), to maintain the halibut bycatch mortality within the specified allowance, (64 FR 56473, October 20, 1999). NMFS since has determined that as of November 6, 1999, 49 mt of halibut mortality remain in the 1999 halibut bycatch mortality allowance specified for the trawl Pacific cod fishery.

Therefore, NMFS is terminating the previous closure and is opening directed fishing for Pacific cod by vessels using trawl gear in the BSAI.

Classification

All other closures remain in full force and effect. This action responds to the best available information recently obtained from the fishery. It must be implemented immediately in order to fully utilize the 1999 halibut bycatch mortality allowance specified for the trawl Pacific cod. Providing prior notice and opportunity for public comment for this action is impracticable and contrary to the public interest. Further delay would only disrupt the FMP objective of utilizing the halibut bycatch mortality allowance to provide Pacific cod TAC for harvest. NMFS finds for good cause that the implementation of this action cannot be delayed for 30 days. Accordingly, under 5 U.S.C. 553(d), a delay in the effective date is hereby waived.

This action is required by § 679.20 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 15, 1999.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 99–30228 Filed 11–16–99; 1:21 pm]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 64, No. 223
Friday, November 19, 1999

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–AAL–18]

Proposed Revision of Class E Airspace; Unalaska, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to revise Class E airspace at Unalaska, AK. The establishment of a Global Positioning System (GPS) instrument approach procedure at Unalaska Airport has made this action necessary. Adoption of this proposal would result in adequate controlled airspace for aircraft flying IFR procedures at Unalaska, AK.

DATES: Comments must be received on or before January 3, 2000.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Operations Branch, AAL–530, Docket No. 99–AAL–18, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587.

The official docket may be examined in the Office of the Regional Counsel for the Alaskan Region at the same address.

An informal docket may also be examined during normal business hours in the Office of the Manager, Operations Branch, Air Traffic Division, at the address shown above and on the Internet at Alaskan Region's homepage at http://www.alaska.faa.gov/at or at address http://162.58.28.41/at.

FOR FURTHER INFORMATION CONTACT: Bob Durand, Operations Branch, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5898; fax: (907) 271–2850; email: Bob.Durand@faa.gov. Internet address: http://www.alaska.faa.gov/at or at address http://162.58.28.41/at.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 99–AAL–18.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the Operations Branch, Air Traffic Division, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

An electronic copy of this document may be downloaded, using a modem and suitable communications software, from the FAA regulations section of the Fedworld electronic bulletin board service (telephone: 703–321–3339) or the **Federal Register**'s electronic bulletin board service (telephone: 202–512–1661).

Internet users may reach the **Federal Register**'s web page for access to recently published rulemaking documents at http://www.access.gpo.gov/su__docs/aces/aces140.html.

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Operations Branch, AAL–530, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587. Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should contact the individual(s) identified in the **FOR FURTHER INFORMATION CONTACT** section.

The Proposal

The FAA proposes to amend 14 CFR part 71 by revising Class E airspace at Unalaska, AK, due to the establishment of a GPS instrument approach procedure. The intended effect of this proposal is to provide additional controlled airspace for IFR operations at Unalaska, AK.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 in FAA Order 7400.9G, *Airspace Designations and Reporting Points*, dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9G, *Airspace Designations and Reporting Points,* dated September 1, 1999, and effective September 16, 1999, is to be amended as follows:

* * * * *

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Unalaska, AK [New]

Unalaska Airport
(Lat. 53°53′57″ N., long. 166°32′42″ W.)
Dutch Harbor NDB
(lat. 53°54′19″ N., long. 166°32′57″ W.)

That airspace extending upward from 700 feet above the surface within 6.4-mile radius of the Unalaska Airport and within 2.9 miles each side of the Dutch Harbor NDB 360° bearing extending from the 6.4-mile radius to 9.5 miles north of the airport; and that airspace extending upward from 1,200 feet above the surface within 20-mile radius north of the airport between the Dutch Harbor NDB 305° bearing extending clockwise to the 075° bearing.

* * * * *

Issued in Anchorage, AK, on November 5, 1999.

Willis C. Nelson,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 99–30262 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

Initiation of Review of Management Plan/Regulations of the Gray's Reef National Marine Sanctuary; Intent To Prepare Draft Environmental Impact Statement and Management Plan; Scoping Meetings

AGENCY: Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce (DOC).

ACTION: Initiation of review of management plan/regulations; intent to prepare environmental impact statement; scoping meetings.

SUMMARY: The Gray's Reef National Marine Sanctuary (GRNMS or Sanctuary) was designated in January 1981, and consists of 17 square nautical miles of open ocean and live bottom habitat approximately 17.5 nautical miles east of Sapelo Island, Georgia. The present management plan for the Sanctuary was completed in 1983. In accordance with Section 304(e) of the National Marine Sanctuaries Act, as amended, (NMSA) (16 U.S.C. 1431 *et seq.*), the Marine Sanctuaries Division (MSD) of the National Oceanic and Atmospheric Administration (NOAA) is initiating a review of the management plan, to evaluate substantive progress toward implementing the goals for the Sanctuary, and to make revisions to the plan and regulations as necessary to fulfill the purposes and policies of the NMSA.

The proposed revised management plan will likely involve changes to existing policies and regulations of the Sanctuary, to address contemporary issues and challenges, and to better protect and manage the Sanctuary's resources and qualities. The review process is composed of four major stages: Information collection and characterization; preparation and release of a draft management plan/environmental impact statement, and any proposed amendments to the regulations; public review and comment; preparation and release of a final management plan/environmental impact statement, and any final amendments to the regulations. NOAA anticipates completion of the revised management plan and concomitant documents will require approximately eighteen to twenty-four months.

NOAA will conduct public scoping meetings to gather information and other comments from individuals, organizations, and government agencies on the scope, types and significance of issues related to the sanctuary's management plan and regulations. The scoping meetings are scheduled for the week of December 6–10, 1999, as detailed below.

DATES: Written comments should be received on or before February 1, 2000.

Scoping meetings will be held at:

(1) Monday, December 6, 1999, 7:00 p.m. in Atlanta, GA.

(2) Tuesday, December 7, 1999, 6:00 p.m. in Brunswick, GA.

(3) Wednesday, December 8, 1999, 7:00 p.m. in Yulee, FL.

(4) Thursday, December 9, 1999, 7:00 p.m. in Richmond Hill, GA.

(5) Friday, December 10, 1999, 4:00 p.m. in Charleston, SC.

ADDRESSES: Written comments may be sent to the Gray's Reef National Marine Sanctuary (Management Plan Review), 10 Ocean Science Circle, Savannah, Georgia 31411. Comments will be available for public review at the same address.

Scoping meetings will be held at:

(1) The Robert Ferst Center for the Arts, Georgia Tech, 349 Ferst Drive, NW, Atlanta, GA 30332.

(2) University of Georgia Marine Extension Service, 715 Bay Street, Brunswick, GA 31520.

(3) Betty P. Cook Nassau County Center, Florida Community College of Jacksonville, 760 William Burgess Blvd., Yulee, FL 32097.

(4) Richmond Hill Holiday Inn, I–95 and Hwy. 17, Exit #14, Richmond Hill, GA 31324.

(5) College of Charleston, Physicians Auditorium, George and Coming Streets, Charleston, SC 29424.

FOR FURTHER INFORMATION CONTACT: Becky Shortland, Planning and Outreach Coordinator, at 912/598–2381 or 2345; Becky.Shortland@noaa.gov.

Authority: 16 U.S.C. Section 1431 *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Ted Lillestolen,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 99–30379 Filed 11–17–99; 2:13 pm]

BILLING CODE 3510–08–M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 767

RIN 0703–AA57

Application Guidelines for Underwater Archeological Research Permits on Submerged Cultural Resources Under the Jurisdiction of the Department of the Navy

AGENCY: Department of the Navy, DOD.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of the Navy (DON) proposes to issue underwater archeological research permits to those applying for permission to recover and/or conduct research on any submerged cultural resource, ship or aircraft wreck, under the jurisdiction of the DON. This action will assist the Navy in managing and protecting its historic underwater cultural resources. This rule will provide clear guidance on the permit application requirements to recover and/or conduct research on submerged Navy properties.

DATES: Submit comments on or before January 18, 2000.

ADDRESSES: Address all comments concerning this rule to Department of the Navy, U.S. Naval Historical Center, Office of the Underwater Archeologist, Building 1, Washington Navy Yard, 805 Kidderbreese Ave. SE, Washington DC 20374–5060. Telefax number: 202–433–2729. Please cite ''Application Guidelines for Underwater Archeological Research Permits.''

FOR FURTHER INFORMATION CONTACT: Dr. Robert S. Neyland, Underwater Archeologist, or Barbara A. Voulgaris, 202–433–2210.

SUPPLEMENTARY INFORMATION:

Background

a. In 1993, DON initiated an archeological management program for its historic ship and aircraft wreck sites. This was aided in part by the U.S. Department of Defense (DoD) Legacy Resource Management Program that was established by Congress in 1991, 10 U.S.C. 114, to provide DoD with an opportunity to enhance the management of DoD stewardship resources. The U.S. Naval Historical Center's (NHC) Office of Underwater Archeology is the Navy command responsible for managing the Navy's submerged cultural resource properties under the guidelines of the Federal Archeological Program.

b. Under the National Historic Preservation Act of 1966 as amended (NHPA), 16 U.S.C. 470 (1999), DON is obligated to protect historic properties, including ship and aircraft wrecks, for which it has custodial responsibilities. The NHPA directs federal agencies to manage their cultural resource properties in a way that emphasizes preservation and minimizes the impact of undertakings that might adversely affect such properties. Management of DON cultural resources such as ship and aircraft wrecks is not simply a matter of preservation. The issues of gravesites, unexploded ordnance, and potential military usage of recovered weapons systems must also be addressed in wrecksite management.

Custody and Management of Navy Shipwrecks and Aircraft Wrecksites

a. DON submerged shipwrecks and aircraft wrecks are government property in the custody of the Navy. These seemingly abandoned wrecks remain government property until specific formal action is taken to dispose of them. Navy custody of its wrecks is based on the property clause of the U.S. Constitution and international maritime law, and is consistent with Articles 95 and 96 of the Law of the Sea Convention. These laws establish that right, title, or ownership of Federal property is not lost to the government due to the passage of time. Navy ships and aircraft cannot be abandoned without formal action as authorized by Congress. Aircraft and ships stricken from the active inventory list are not considered formally disposed of or abandoned. Through the sovereign immunity provisions of admiralty law, DON retains custody of all its naval vessels and aircraft, whether lost in U.S., foreign, or international boundaries.

b. Divers may dive on Navy wrecks at their own risk; however, Federal property law dictates that no portion of a government wreck may be disturbed or removed. The Navy strongly encourages cooperation with other agencies and individuals interested in preserving our maritime and aviation heritage. Diving on sunken Navy ships and aircraft located in units of the national park system or the national marine sanctuary system may be prohibited unless authorized by a Federal land manager.

c. The diving public is encouraged to report the location of underwater ship and aircraft wrecksites to the NHC. Documentation of these wreck locations allows the Navy to evaluate and preserve important sites for the future. Under no circumstances will salvage of Navy aircraft or shipwrecks be undertaken without prior and specific written approval by the NHC.

d. Wrecksites that are not entire aircraft or ships, but are parts strewn in a debris field, are considered potential archeological sites. Such sites still contain Navy property and must be managed by the Navy in accordance with the NHPA, the Secretary of the Interior's Standards and Guidelines on Archeology and Historic Preservation, 48 FR 44716 (1983), and departmental regulations. Permits for recovery of submerged Navy ship or aircraft wrecks will be considered only for educational or scientific reasons. It is unlikely DON will recommend the disposal and sale of a Navy ship or aircraft wreck that is eligible for listing on the National Register of Historic Places. The Navy maintains a policy of not disposing wrecked ships and aircraft for the following reasons:

1. Congress has mandated through the NHPA that the DON make every effort to preserve its historic cultural resources;

2. The remains of crewmembers, if any, deserve to be treated with honor and dignity and to be properly retrieved for burial if possible;

3. There is a possibility that live explosives or ordnance may still be associated with the vessel or aircraft;

4. The arbitrary disposal and sale of wrecks may foster commercial exploitation of cultural resources and;

5. The abandonment of wrecks could deplete a finite inventory of significant cultural resources.

e. Because of the large number of aircraft wrecks and because they are generally easier to recover and conserve than shipwrecks, DON does consider and encourage requests for loans of historic aircraft. Museums or other private parties interested in the recovery of Navy aircraft for educational or scientific purposes should contact the NHC for guidance.

List of Subjects in 32 CFR Part 767

Aircraft, Archeology, Educational research, Government property, Government property management, Historic preservation, Permit, Research, Scientific research, Vessel.

For the reasons stated in the preamble, the Department of the Navy proposes to add 32 CFR part 767 to read as follows:

PART 767—APPLICATION GUIDELINES FOR UNDERWATER ARCHEOLOGICAL RESEARCH PERMITS ON SUBMERGED CULTURAL RESOURCES UNDER THE JURISDICATION OF THE DEPARTMENT OF THE NAVY

Subpart A—Regulations and Obligations

Sec.
767.1 Purpose.
767.2 Definitions.
767.3 Policy.

Subpart B—Permit Guidelines

767.4 Application for permit.
767.5 Evaluation of permit application.
767.6 Credentials of principal investigator.
767.7 Conditions of permits.
767.8 Requests for amendments or extensions of active permits.
767.9 Content of permit holder's final report.
767.10 Monitoring of performance.
767.11 Violations of permit conditions.
767.12 References for submission of permit application to conduct archeological research.

Authority: 5 U.S.C. 301; 16 U.S.C. 470.

Subpart A—Regulations and Obligations

§ 767.1 Purpose.

(a) The purpose of this part is to establish the requirement and procedural guidelines for permits to recover and/or conduct research on Department of the Navy (DON) submerged cultural resources.

(b) The U.S. Naval Historical Center's (NHC) Office of Underwater Archeology is the Navy command responsible for managing Navy submerged cultural resource properties under the guidelines of the Federal Archeological Program. In order for the NHC's management policy to be consistent with the Federal Archeology Program, and the goals of the NHPA, the Navy has implemented a permitting process applicable to Navy property consistent with and applying the Archeological Resources Protection Act of 1979 (ARPA), 16 U.S.C. 470aa–470ll (1999), permitting criteria. Navy policies regarding its submerged cultural resources, to include ship and aircraft wrecks are consistent with ARPA permitting requirements. Navy application of ARPA permitting criteria promotes consistency among federal agencies and meets the Navy's responsibilities under the NHPA, while allowing qualified non-federal and private individuals and entities access to Navy historic vessel and aircraft wrecks.

(c) To assist NHC in managing, protecting, and preserving DON submerged cultural resources.

§ 767.2 Definitions.

Aircraft wrecksite means the location where an aircraft has been crashed, ditched, damaged, or stranded. The wreck may be intact or scattered, may be on land or in water, and may be a structure or a site.

Archeological site means the location of a significant event, historic occupation or activity, or a building or structure including aircraft or shipwrecks, whether standing, ruined, or vanished, and its debris field where the location itself retains historical or archeological value regardless of the value of any existing structure.

Artifact means any object or assemblage of objects found in an archeological context that yields or is likely to yield information of significance to the scientific study of culture or human history.

Cultural resource means the remains or records of districts, sites, structures, buildings, networks, objects, and events from the past. They may be historic, archeological, or architectural in nature. Cultural resources are an irreplaceable and nonrenewable aspect of our national heritage.

Gravesite means any natural or prepared physical location, whether originally below, on, or above the surface of the earth, where individual human remains are deposited.

Permit holder means any person authorized and given the exclusive right by the NHC to conduct any activity under these regulations.

Permitted activity means any activity that is authorized by the NHC under these regulations.

Research vessel means any vessel employed for scientific purposes under these regulations.

Shipwreck means the physical remains of a vessel, its cargo, and other contents.

Wrecksite means the location of a ship or aircraft that has been sunk, crashed, ditched, damaged, or stranded. The wreck may be intact or scattered, may be on land or in water, and may be a structure or a site. The site includes the physical remains of the wreck and all other associated artifacts.

§ 767.3 Policy.

(a) The NHC's policy has been to evaluate each Navy submerged cultural resource on an individual basis. In some cases, the removal of Navy submerged cultural resources may be necessary or appropriate to protect the resource and/or to fulfill other NHC goals, such as those encompassing research, education, public access, and appreciation. Recovery of Navy submerged cultural resources may be justified in specific cases where the existence of a resource may be threatened. Therefore, recovery of some or all of a resource may be permitted for identification and/or investigation to answer specific questions; or the recovery presents an opportunity for public research or education.

(b) Generally, submerged Navy cultural resources will be left in place unless artifact removal or site disturbance is justified and necessary to protect Navy cultural resources, to conduct research, or provide public education and information that is otherwise inaccessible. While the NHC prefers non-destructive, in situ research on submerged Navy shipwrecks and aircraft wrecks, it recognizes that site disturbance and/or artifact recovery is sometimes necessary. At such times, site disturbance and/or archeological recovery may be permitted, subject to conditions specified by NHC.

Subpart B—Permit Guidelines

§ 767.4 Application for permit.

(a) To request a permit application form, please write to: Department of the Navy, U.S. Naval Historical Center, Office of the Underwater Archeologist, Building 1, Washington Navy Yard, 805 Kidderbreese Ave. SE, Washington DC 20374–5060. Telefax number: 202–433–2729.

(b) Applicants must submit three copies of their completed application at least 90 days in advance of the requested effective date to allow sufficient time for evaluation and processing. Requests should be sent to the Underwater Archeologist of the U.S. Navy, Naval Historical Center, Washington Navy Yard, 805 Kidderbreese Ave. SE, Washington, DC 20374–5060.

(c) If the applicant believes that compliance with one or more of the factors, criteria, or procedures in the guidelines contained in this part is not practicable, the applicant should set forth why and explain how the purposes of the NHC are better served without compliance with the specified requirements. Permits are valid for six months from the issue date.

§ 767.5 Evaluation of permit application.

(a) Permit applications for archeological research are reviewed for completeness, compliance with program policies, and adherence to these guidelines. Incomplete applications will be returned to the applicant for clarification. Complete applications are reviewed by NHC personnel and, when necessary, outside experts. In addition to the criteria set forth in § 767.6,

applications are also judged on the basis of: relevance or importance; archeological merits; appropriateness and environmental consequences of technical approach; whether the proposed effort would be more appropriately conducted outside of the NHC; and qualifications of the applicants.

(b) Under certain circumstances, it may be necessary to consult with the State Historic Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP) about the need to comply with section 106 of the NHPA. A section 106 review requires the NHC to consult with the appropriate SHPO and the ACHP. The ACHP review can take up to 60 days beyond the NHC's required 90-day review. Therefore, the entire review process may take up to 150 days.

(c) Applications for research at sites located in units of the National Park system, national wildlife refuge system, and national marine sanctuary system, shall be sent to the appropriate Federal land manager for review. Applications for research at sites located on state bottomlands should be sent to the appropriate state agency for review. The burden of obtaining any and all additional permits or authorizations, such as from a state or foreign government or agency, private individual or organization, or from another federal agency, is on the applicant.

(d) Based on the findings of the NHC evaluation, the NHC Underwater Archeologist will recommend an appropriate action to the NHC Director. If approved, the NHC will issue the permit; if denied, applicants are notified of the reason for denial and may appeal within 30 days of receipt of the denial. Appeals must be submitted in writing to: Director of Naval History, Naval Historical Center, 805 KidderBreese Ave. SE, Washington, DC 20374–5060.

§ 767.6 Credentials of principal investigator.

A resume or curriculum vitae detailing the professional qualifications and professional publications and papers of the principal investigator (PI) must be submitted with the permit application. The PI must have: a graduate degree in archeology, anthropology, maritime history, or a closely related field; at least one year of professional experience or equivalent specialized training in archeological research, administration or management; at least four months of supervised field and analytic experience in general North American historic archaeology and maritime history; the demonstrated ability to carry research to completion; and at least one year of full-time professional experience at a supervisory level in the study of historic marine archeological resources. This person shall be able to demonstrate ability in comprehensive analysis and interpretation through authorship of reports and monographs.

§ 767.7 Conditions on permits.

(a) Upon receipt of a permit, permit holders must counter-sign the permit and return copies to the NHC and the applicable SHPO prior to conducting permitted activities on the site. Copies of countersigned permits should also be provided to the applicable federal land manager when the sunken vessel or aircraft is located within a unit of the national park system, the national wildlife refuge system, or the national marine sanctuary system.

(b) Permits must be carried aboard research vessels and made available upon request for inspection to regional preservation personnel or law enforcement officials. Only persons named in the permit may participate in permitted activities. Permits are non-transferable. Permit holders must abide by all provisions set forth in the permit as well as applicable state or Federal regulations. Permit holders should abide by applicable regulations of a foreign government when the sunken vessel or aircraft is located in foreign waters. To the extent reasonably possible, the environment must be returned to the condition that existed before the activity occurred.

(c) Upon completion of permitted activities, the permit holder is required to submit to the NHC a working and diving log listing days spent in field research, activities pursued, and working area positions.

(d) The permit holder must prepare and submit a final report as detailed in § 767.9, summarizing the results of the permitted activity.

(e) The permit holder must agree to protect all sensitive information regarding the location and character of the wreck site that could potentially expose it to non-professional recovery techniques, looters, or treasure hunters. Sensitive information includes specific location data such as latitude and longitude, and information about a wreck's cargo, the existence of armaments, or the knowledge of gravesites.

(f) All recovered DON cultural resources remain the property of the United States. These resources and copies of associated archaeological records and data will be preserved by a suitable university, museum, or other scientific or educational institution.

§ 767.8 Requests for amendments or extensions of active permits.

(a) Requests for amendments to active permits (e.g., a change in study design or other form of amendment) should conform to these guidelines. All necessary information to make an objective evaluation of the amendment should be included as well as reference to the original application.

(b) Permit holders desiring to continue research activities must reapply for an extension of their current permit before it expires. A pending extension or amendment request does not guarantee extension or amendment of the original permit. Therefore, you must submit an extension request to the NHC at least 30 days prior to the original permit's expiration date. Reference to the original application may be given in lieu of a new application, provided the scope of work does not change significantly. Applicants may apply for no more than two six-month extensions.

(c) Permit holders may appeal denied requests for amendments or extensions to the appeal authority listed in § 767.5.

§ 767.9 Content of permit holder's final report.

The permit holder's final report shall include the following:

(a) A site history and a contextual history relating the site to the general history of the region;

(b) A master site map;

(c) Feature map(s) of the location of any recovered artifacts in relation to their position within the wrecksite;

(d) Photographs of significant site features and significant artifacts both in situ and after removal;

(e) A description of the conservation of artifact lists, laboratory conservation records, and before and after photographs of significant artifacts at the conservation laboratory;

(f) A written report describing the historical background, environment, archeological field work, results, and analysis;

(g) A summary of the survey and/or excavation process;

(h) An evaluation of the completed permitted activity that includes an assessment of the permit holder's success of his/her specified goals.

§ 767.10 Monitoring of performance.

Permitted activities will be monitored to ensure compliance with the conditions of the permit. NHC on-site personnel, or other designated authorities, may periodically assess

work in progress by visiting the study location and observing any activity allowed by the permit or by reviewing any required reports. The discovery of any potential irregularities in performance under the permit will be promptly reported and appropriate action will be taken. Permitted activities will be evaluated and the findings will be used to evaluate future applications.

§ 767.11 Violations of permit conditions.

The Director of the NHC, the Underwater Archeologist for DON, or his/her designee may amend, suspend, or revoke a permit in whole or in part, temporarily or indefinitely, if in his/her view the permit holder has acted in violation of the terms of the permit or of other applicable regulations, or for other good cause shown. Any such action will be communicated in writing to the permit holder and will set forth the reason for the action taken. The permit holder may appeal the action to the appeal authority listed in § 767.5.

§ 767.12 References for submission of permit application to conduct archeological research.

(a) National Historic Preservation Act of 1966, as amended (NHPA), 16 U.S.C. 470 *et seq.* (1999), and Protection of Historic Properties, 36 CFR part 800 (1999). These regulations govern the Section 106 Review Process established by the NHPA.

(b) Secretary of the Interior's Standards and Guidelines for Archeology and Historic Preservation, 48 FR 44716 (1983). This publication establishes standards for the preservation planning process with guidelines on implementation.

(c) Archeological Resources Protection Act of 1979, as amended (ARPA), 16 U.S.C. 470aa *et seq.* (1999), and the Uniform Regulations, ARPA, 43 CFR part 7 (1998). These regulations establish basic government-wide standards for the issuance of permits for archeological research, including the authorized excavation and/or removal of archeological resources on public lands or Indian lands.

(d) Secretary of the Interior's Curation of Federally-Owned and Administered Archeological Collections, 36 CFR part 79 (1999). This publication establishes standards for the curation and display of federally-owned artifact collections.

(e) Antiquities Act of 1906, Pub. L. No. 59–209, 34 Stat. 225 (codified at 16 U.S.C. 431 *et seq.* (1999)).

(f) Executive Order No. 11593, 36 FR 8291, 3 CFR, 1971–1975 Comp., p. 559 (Protection and Enhancement of the Cultural Environment).

(g) Department of Defense Instruction 4140.21M (DoDI 4120.21M, August 1998). Subject: Defense Disposal Manual.

(h) Secretary of the Navy Instruction 4000.35 (SECNAVINST 4000.35, 17 August 1992). Subject: Department of the Navy Cultural Resources Program.

(i) Naval Historical Center Instruction 5510.4. (NAVHISTCENINST 5510.4, 14 December 1995). Subject: Disclosure of Information from the Naval Shipwreck Database.

Christopher G. Carlson,

Major, USMC, Alternate Federal Register Liaison Officer.

[FR Doc. 99–30079 Filed 11–18–99; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Chapter I

[USCG–1998–4501]

RIN 2115–AF68

Improvements to Marine Safety in Puget Sound-Area Waters

AGENCY: Coast Guard, DOT.

ACTION: Notice of rescheduled meeting.

SUMMARY: The Coast Guard announces the rescheduling of the two meetings to describe the results of and solicit comments on the cost-benefit analysis of potential rules that could improve marine safety in Puget Sound-Area waters. These meetings, originally scheduled for Tuesday November 16, 1999 and Wednesday November 17, 1999 (64 FR 56286, October 19, 1999), will now be conducted on December 10, 1999. Under consideration are regulatory requirements for tug escorts and/or dedicated rescue tugs for certain vessels operating in the Strait of Juan de Fuca and adjacent waters.

DATES: The meetings will be held from 9:00 AM to 12:00 PM and from 2:00 PM to 5:00 PM on Friday December 10, 1999, with additional time for questions to the regulatory analysis study team from 12:00 PM to 1:00 PM. Comments to the docket for the advance notice of proposed rulemaking must reach the Docket Management Facility on or before January 31, 2000.

ADDRESSES: The public meeting will be held at the Jackson Federal Building Auditorium, 915 Second Avenue, Seattle, WA 98174–1067.

You may submit your written comments and related material by only one of the following methods:

(1) By mail to the Docket Management Facility, (USCG–1999–4501), U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(2) By hand to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) Electronically through the Web Site for the Docket Management System at http://dms.dot.gov.

The Docket Management Facility maintains the public docket for this notice. Comments and documents, as indicated in this notice, will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza Level of the Nassif Building at the same address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may electronically access the public docket for this notice on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: For questions on the public meeting, contact CDR Timothy M. Close, Human Element and Ship Design Division (G–MSE–1), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001, telephone 202–267–2997, fax 202–267–4816, email *fldr-he@comdt.uscg.mil*. For questions on viewing or submitting material to the docket, call Dorothy Walker, Chief, Dockets, Department of Transportation, telephone 202–366–9329.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate by submitting comments and related material. If you do so, please include your name and address, identify the docket number [USCG–1998–4501], indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by mail, hand delivery, fax, or electronic means to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this rule in view of them.

Public Meeting

The purpose of the meeting is to describe the results of the cost-benefit analysis. Also, as time allows, the Coast Guard will respond to questions about the cost-benefit analysis, and discuss how the results will be used. Attendance is open to the public.

Background and Purpose

This meeting has been rescheduled to allow time for the contracted study team to finalize the report. The purpose of the meeting is to provide the public with a briefing on the results of the cost-benefit analysis. Comments to the docket regarding the results of the cost-benefit analysis and their interpretation are encouraged. The analysis and these comments will be used by the Navigation Safety Advisory Council panel formed to develop a long-term oil-spill risk management plan for the region (64 FR 48442, September 3, 1999) and by the Secretary in the final determination regarding the regulatory measures under consideration. The cost-benefit study will be available from the Coast Guard's Marine Safety and Environmental Protection Internet site at *http://www.uscg.mil/hq/g-m/gmhome.*

Information on Services for the Handicapped

Contact CDR Close for information on facilities or services for the handicapped or to request special assistance at the meetings as soon as possible.

Dated: November 16, 1999.

Jeffrey High,

Acting Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 99–30270 Filed 11–16–99; 3:05 pm]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–99–182]

RIN 2115–AA97

Safety Zone: New York Cruise Lines Fireworks, New York Harbor, Upper Bay

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone in Federal Anchorage 20C, New York Harbor, Upper Bay, for the New York Cruise Lines Fireworks display. This action is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in Federal Anchorage 20C.

DATES: Comments must reach the Coast Guard on or before December 20, 1999.

ADDRESSES: Comments may be mailed to the Waterways Oversight Branch (CGD01–99–182), Coast Guard Activities New York, 212 Coast Guard Drive, Staten Island, New York 10305, or deliver them to room 205 at the same address between 8 a.m. and 3 p.m., Monday through Friday, except federal holidays.

The Waterways Oversight Branch of Coast Guard Activities New York maintains the public docket for this rulemaking. Comments, and documents as indicated in this preamble, will become part of this docket and will be available for inspection or copying at room 205, Coast Guard Activities New York, between 8 a.m. and 3 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant J. Lopez, Waterways Oversight Branch, Coast Guard Activities New York (718) 354–4193.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD01–99–182) and the specific section of this document to which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard will consider all comments received during the comment period. It may change this proposed rule in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Waterways Oversight Branch at the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

Fireworks by Grucci has submitted an Application for Approval of a Marine Event for a fireworks display on the waters of Upper New York Bay in Federal Anchorage 20C. This proposed regulation establishes a temporary safety zone in all waters of Upper New York Bay in Federal Anchorage 20C within a 360-yard radius of the fireworks barge in approximate position 40°41′16.6″N 074°02′23″W (NAD 1983), approximately 360 yards east of Liberty Island, New York. The proposed safety zone would be effective from 10:30 p.m. Friday, December 31, 1999, to 12:45 a.m. Saturday, January 1, 2000. The rain date for this event would be 10:30 p.m. Saturday, January 1, 2000, to 12:45 a.m. Sunday, January 2, 2000, at the same location. The proposed safety zone prevents vessels from transiting a portion of Federal Anchorage 20C, and is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area. Marine traffic will still be able to anchor in the unaffected northern and southern portions of Federal Anchorage 20C. Federal Anchorages 20A and 20B, to the north, and Federal Anchorages 20D and 20E, to the south, are also available for vessel use. Marine traffic will still be able to transit through Anchorage Channel, Upper Bay, during the event as the proposed safety zone only extends 125 yards into the 925-yard wide channel. The Captain of the Port does not anticipate any negative impact on vessel traffic due to this event. Public notifications will be made prior to the event via local notice to mariners, and marine information broadcasts. The Coast Guard is limiting the comment period for this NPRM to 30 days because the proposed safety zone is only for a two hour and fifteen minute long local event and it should have negligible impact on vessel transits. The Coast Guard expects to receive no comments on this NPRM due to the limited duration of the event and the fact that it should not interfere with vessel transits.

Discussion of Proposed Rule

The proposed safety zone is for the New York Cruise Lines Fireworks display held on the Upper New York Bay in Federal Anchorage 20C. This event will be held on Friday, December 31, 1999. The rain date for this event is Saturday, January 1, 2000, at the same time and place. This rule is being proposed to provide for the safety of life on navigable waters during the event and to give the marine community the opportunity to comment on this event.

Regulatory Evaluation

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It has not been reviewed by the Office of Management and Budget under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. Although this regulation prevents traffic from transiting a portion of the Upper New York Bay, Federal Anchorage 20C during the event, the effect of this regulation will not be significant for several reasons: the minimal time that vessels will be restricted from the area, that vessels may safely anchor to the north and south of the zone, that vessels may still transit through Anchorage Channel during the event, and advance notifications which will be made to the local maritime community by the Local Notice to Mariners, and marine information broadcasts.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this proposed rule, if adopted, will have a significant economic impact on a substantial number of small entities. ''Small entities'' include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

For reasons stated in the Regulatory Evaluation section above, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule, if adopted, will not have a significant economic impact on a substantial number of small entities. If, however, you think that your business or organization qualifies as a small entity and that this proposed rule will have a significant economic impact on your business or organization, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and in what way and to what degree this proposed rule will economically affect it.

Collection of Information

This proposed rule does not provide for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this proposed rule under the principles and criteria contained in Executive Order 13132 and has determined that this proposed rule does not have implications for federalism under that Order.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) [Pub. L. 104–4, 109 Stat. 48] requires Federal agencies to assess the effects of certain regulatory actions on State, local, and tribal governments, and the private sector. UMRA requires a written statement of economic and regulatory alternatives for rules that contain Federal mandates. A ''Federal mandate'' is a new or additional enforceable duty imposed on any State, local, or tribal government, or the private sector. If any Federal mandate causes those entities to spend, in the aggregate, $100 million or more in any one year, the UMRA analysis is required. This proposed rule would not impose Federal mandates on any State, local, or tribal governments, or the private sector.

Environment

The Coast Guard has considered the environmental impact of this proposed rule and concluded that under figure 2–1, paragraph 34(g), of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation. A written Categorical Exclusion Determination is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

Proposed Regulation

For the reasons set out in the preamble, the Coast Guard proposes to amend 33 CFR Part 165 as follows:

PART 165—[AMENDED]

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. Add temporary § 165.T01–182 to read as follows:

§ 165.T01–182 Safety Zone: New York Cruise Lines Fireworks, New York Harbor, Upper Bay.

(a) *Location.* The following area is a safety zone: All waters of New York Harbor, Upper Bay within a 360-yard radius of the fireworks barge in approximate position 40°41′16.5″N 074°02′23″W (NAD 1983), approximately 360 yards east of Liberty Island, New York.

(b) *Effective period.* This section is effective from 10:30 p.m. Friday, December 31, 1999, to 12:45 a.m. Saturday, January 1, 2000. If the event is canceled due to inclement weather, then this section would be effective from 10:30 p.m. Saturday, January 1, 2000, to 12:45 a.m. Sunday, January 2, 2000.

(c) *Regulations.* (1) The general regulations contained in 33 CFR 165.23 apply.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene-patrol personnel. These personnel comprise commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

Dated: November 9, 1999.

R.E. Bennis,

Captain, U. S. Coast Guard, Captain of the Port, New York.

[FR Doc. 99–30268 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–15–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 235–184; FRL–6478–2]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, Tehama County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes a limited approval of revisions to the California State Implementation Plan (SIP) concerning control of volatile organic compound (VOC) emissions from organic solvents.

The intended effect of proposing limited approval of this rule is to regulate emissions of VOCs in accordance with the requirements of the Clean Air Act, as amended in 1990

(CAA or the Act). EPA's final action on this proposed rulemaking will incorporate this rule into the federally approved SIP. EPA has evaluated the rule and is proposing a limited approval under provisions of the CAA regarding EPA action on SIP submittals and general rulemaking authority because these revisions, while strengthening the SIP, also do not fully meet the CAA provisions regarding plan submissions.

DATES: Comments must be received on or before December 20, 1999.

ADDRESSES: Comments may be mailed to: Andrew Steckel, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rule and EPA's evaluation report of the rule is available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rule is also available for inspection at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95814.

Tehama County Air Pollution Control District, 1750 Walnut Street, P.O. Box 38, Red Bluff, CA 96080.

FOR FURTHER INFORMATION CONTACT: Andrew Steckel, Rulemaking Office, (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901; Telephone: (415) 744–1185.

SUPPLEMENTARY INFORMATION:

I. Applicability

The rule being proposed for limited approval into the California SIP is: Tehama County Air Pollution Control District (THCAPCD) Rule 4.22, Industrial Use of Organic Solvents. This rule was submitted by the California Air Resources Board (CARB) to EPA on November 25, 1987.

II. Background

40 CFR 81.305 provides the attainment status designations for air districts in California. Tehama County is listed as being in attainment for the national ambient air quality standard (NAAQS)for ozone. Therefore for the purpose of controlling ozone, this rule only needs to comply with section 110 of the Act.

The State of California submitted many revised rules to EPA for incorporation into its SIP on November 25, 1987, including the rule being acted on in this document. This document addresses EPA's proposed action for Rule 4.22, Industrial Use of Organic Solvents. Tehama County adopted Rule 4.22 on August 4, 1987. This submitted rule is being proposed for limited approval. Rule 4.22 controls the emission of volatile organic compounds (VOCs) from industrial use of organic solvents. VOCs are a precursor for ozone. The following is EPA's evaluation and proposed action for THCAPCD Rule 4.22.

III. EPA Evaluation and Proposed Action

In determining the approvability of a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittals of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in various EPA policy guidance documents.[1] THCAPCD's Rule 4.22 applies to a source category that is not covered by an applicable CTG and therefore state and local agencies may determine what controls are required by reviewing the operation of facilities subject to the regulation and evaluating regulations for similar sources in other areas. Further interpretations of EPA policy are found in the Blue Book, referred to in footnote 1. In general, the EPA guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP. While Tehama County is in attainment with the ozone NAAQS, many of the general SIP requirements regarding enforceability, for example, are still appropriate for this rule.

There is currently no version of THCAPCD, Rule 4.22, Industrial use of Organic Solvents in the SIP. The submitted rule includes the following significant provisions:

- *Section (a)* a prohibition of discharges of more than 15 lbs of VOCs from any article, machine, equipment or contrivance in which organic solvents or any material containing organic solvents comes into contact with flame or is baked, heat cured, or heat polymerized, in the presence of oxygen at temperatures above 400°F.
- *Section (b)* a prohibition against discharging more than 40 lbs of VOCs from any article, machine, equipment or contrivance used under conditions other than described under (a).
- The rule allows the use of emission control equipment to reduce the discharge to no more than the limits specified in sections (a) and (b).
- *Section (d)(1)* establishes a VOC daily maximum emission limit of 450 lbs for facilities applying polyester resins in fiberglass reinforced plastic fabrication.
- Incorporates by reference VOC emission limits and other provisions contained in 40 CFR 52.254, November 12, 1973, Volume 38, No. 217.

EPA has evaluated THCAPCD's submitted Rule 4.22 for consistency with the CAA, EPA regulations, and EPA policy and has found that the rule will strengthen the SIP. However the rule contains the following deficiencies:

- A director's discretion to choose and approve test methods to determine conformance,
- Lack of specified test methods or monitoring protocol,
- No recordkeeping provisions.

A detailed discussion of the rule deficiencies can be found in the Technical Support Document for THCAPCD Rule 4.22, which is available from the U.S. EPA, Region IX office.

Because the deficiencies identified in this rule may cause enforceability problems, EPA cannot grant full approval under 110(k)(3). Also, because the submitted rule is not composed of separable parts which meet all the applicable parts of the CAA, EPA cannot grant partial approval of the rule under section 110(k)(3). However, EPA may grant a limited approval of the submitted rule under section 110(k)(3) in light of EPA's authority pursuant to section 301(a) to adopt regulations to advance the Act's air quality protection goals by strengthening the SIP. In order to strengthen the SIP by advancing the ozone air quality protection goal of the Act, EPA is proposing a limited approval of THCAPCD's Rule 4.22 under sections 110(k)(3) and 301(a) of the Act. However this limited approval would not approve Rule 4.22 as satisfying any other specific requirement of the act, nor would it constitute full approval of Rule 4.22 pursuant to section 110(k)(3). Rather, a limited approval of this rule by EPA would mean that the emission limitations and other control measure requirements become part of the California SIP and are federally enforceable by EPA. See, *e.g.* sections 302(q) and 113 of the Act.

[1] Among other things, the pre-amendment guidance consists of those portions of the proposed post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to appendix D of November 24, 1987 **Federal Register** document'' (Blue Book) (notice of availability was published in the **Federal Register** on May 25, 1988); and the existing control technique guidelines (CTGs).

It should be noted that the rule covered by this proposed rulemaking has been adopted by and is currently in effect in TCAPCD. EPA's final limited approval action will not prevent THCAPCD or EPA from enforcing this rule.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, Regulatory Planning and Review.

B. Executive Order 13132

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612, Federalism and 12875, Enhancing the Intergovernmental Partnership. Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This rule is not subject to E.O. 13045 because it is does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.*, v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping

requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: November 5, 1999.

Laura Yoshii,

Acting Regional Administrator, Region IX.

[FR Doc. 99–30237 Filed 11–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CO–001–035b; UT–001–0023b; WY–001–0004b; FRL–6471–5]

Approval and Promulgation of Air Quality Implementation Plans; States of Colorado, Utah and Wyoming; General Conformity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing approval of the State Implementation Plan (SIP) revisions submitted by the States of Colorado, Utah and Wyoming incorporating the General Conformity provisions of 40 CFR part 51, subpart W, and 40 CFR part 93, subpart B. The implementation plan revisions were submitted by these States to satisfy the requirements of section 176(c) of the Clean Air Act for revisions to the SIP which contain criteria and procedures for assessing the conformity of Federal actions to the applicable implementation plan. These States have incorporated the Federal General Conformity provisions into their SIPs by reference. Additional information is available at the address indicated below. In the Final Rules section of this **Federal Register**, EPA is approving the States' SIP revisions as a direct final rule without prior proposal because the Agency views these as noncontroversial revisions and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed rule must be received in writing by December 20, 1999.

ADDRESSES: Written comments should be addressed to: Richard R. Long, Director, Air & Radiation Program (8P–AR), United States Environmental Protection Agency, Region 8, 999 18th Street, Suite 500, Denver, Colorado 80202–2466.

Copies of the documents relevant to this action are available for public inspection between 8 a.m. and 4 p.m., Monday through Friday at the following office: United States Environmental Protection Agency, Region 8, Air & Radiation Program, 999 18th Street, Suite 500, Denver, Colorado 80202–2466.

FOR FURTHER INFORMATION CONTACT: Jeff Houk, Air & Radiation Program (8P–AR), United States Environmental Protection Agency, Region 8, 999 18th Street, Suite 500, Denver, Colorado 80202–2466; ph. (303) 312–6446.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action which is located in the Rules section of this **Federal Register**.

Dated: October 13, 1999

Jack W. McGraw,

Acting Regional Administrator, Region VIII.

[FR Doc. 99–30233 Filed 11–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 55

[FRL–6478–3]

Outer Continental Shelf Air Regulations Consistency Update for California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; consistency update.

SUMMARY: EPA is proposing to update a portion of the Outer Continental Shelf (''OCS'') Air Regulations. Requirements applying to OCS sources located within 25 miles of states' seaward boundaries must be updated periodically to remain consistent with the requirements of the corresponding onshore area (''COA''), as mandated by section 328(a)(1) of the Clean Air Act, as amended in 1990 (''the Act''). The portion of the OCS air regulations that is being updated pertains to the requirements for OCS sources for which the Santa Barbara County Air Pollution Control District (Santa Barbara County APCD) and Ventura County Air Pollution Control District (Ventura County APCD) are the designated COAs. The intended effect of approving the OCS requirements for the above Districts, contained in the Technical Support Document, is to regulate emissions from OCS sources in accordance with the requirements onshore. The changes to the existing requirements discussed below are proposed to be incorporated by reference into the Code of Federal Regulations and are listed in the appendix to the OCS air regulations.

DATES: Comments on the proposed update must be received on or before December 20, 1999.

ADDRESSES: Comments must be mailed (in duplicate if possible) to: EPA Air Docket (Air-4), Attn: Docket No. A–93–16 Section XIX, Environmental Protection Agency, Air Division, Region 9, 75 Hawthorne St., San Francisco, CA 94105.

DOCKET: Supporting information used in developing the rule and copies of the documents EPA is proposing to incorporate by reference are contained in Docket No. A–93–16 Section XIX. This docket is available for public inspection and copying Monday–Friday during regular business hours at the following locations:

EPA Air Docket (Air-4), Attn: Docket No. A–93–16 Section XIX, Environmental Protection Agency, Air Division, Region 9, 75 Hawthorne St., San Francisco, CA 94105.

EPA Air Docket (LE–131), Attn: Air Docket No. A–93–16 Section XIX, Environmental Protection Agency, 401 M Street SW, Room M–1500, Washington, DC 20460.

A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, Air Division (Air-4), U.S. EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105, (415) 744–1197.

SUPPLEMENTARY INFORMATION:

I. Background

On September 4, 1992, EPA promulgated 40 CFR part 55,[1] which established requirements to control air pollution from OCS sources in order to attain and maintain federal and state ambient air quality standards and to comply with the provisions of part C of title I of the Act. Part 55 applies to all OCS sources offshore of the States except those located in the Gulf of Mexico west of 87.5 degrees longitude. Section 328 of the Act requires that for

[1] The reader may refer to the Notice of Proposed Rulemaking, December 5, 1991 (56 FR 63774), and the preamble to the final rule promulgated September 4, 1992 (57 FR 40792) for further background and information on the OCS regulations.

such sources located within 25 miles of a state's seaward boundary, the requirements shall be the same as would be applicable if the sources were located in the COA. Because the OCS requirements are based on onshore requirements, and onshore requirements may change, section 328(a)(1) requires that EPA update the OCS requirements as necessary to maintain consistency with onshore requirements.

Pursuant to § 55.12 of the OCS rule, consistency reviews will occur (1) At least annually; (2) Upon receipt of a Notice of Intent under § 55.4; or (3) When a state or local agency submits a rule to EPA to be considered for incorporation by reference in part 55. This proposed action is being taken in response to the submittal of rules by two local air pollution control agencies. Public comments received in writing within 30 days of publication of this document will be considered by EPA before publishing a final rule.

Section 328(a) of the Act requires that EPA establish requirements to control air pollution from OCS sources located within 25 miles of states' seaward boundaries that are the same as onshore requirements. To comply with this statutory mandate, EPA must incorporate applicable onshore rules into part 55 as they exist onshore. This limits EPA's flexibility in deciding which requirements will be incorporated into part 55 and prevents EPA from making substantive changes to the requirements it incorporates. As a result, EPA may be incorporating rules into part 55 that do not conform to all of EPA's state implementation plan (SIP) guidance or certain requirements of the Act.

Consistency updates may result in the inclusion of state or local rules or regulations into part 55, even though the same rules may ultimately be disapproved for inclusion as part of the SIP. Inclusion in the OCS rule does not imply that a rule meets the requirements of the Act for SIP approval, nor does it imply that the rule will be approved by EPA for inclusion in the SIP.

II. EPA Evaluation and Proposed Action

In updating 40 CFR part 55, EPA reviewed the rules submitted for inclusion in part 55 to ensure that they are rationally related to the attainment or maintenance of federal or state ambient air quality standards or part C of title I of the Act, that they are not designed expressly to prevent exploration and development of the OCS and that they are applicable to OCS sources. 40 CFR 55.1. EPA has also evaluated the rules to ensure they are not arbitrary or capricious. 40 CFR 55.12(e). In addition, EPA has excluded administrative or procedural rules,[2] and requirements that regulate toxics which are not related to the attainment and maintenance of federal and state ambient air quality standards.

A. After review of the rules submitted by Santa Barbara County APCD against the criteria set forth above and in 40 CFR part 55, EPA is proposing to make the following rules applicable to OCS sources for which the Santa Barbara County APCD is designated as the COA:

1. *The following rule was submitted as a revision to existing requirements:*

Rule 102 Definitions (Adopted 5/10/99)

2. *The following new rules were submitted:*

Rule 106 Notice to Comply for Minor Violations (Adopted 7/5/99)
Rule 352 Natural-Gas Fired Fan-Type Central Furnaces and Residential Water Heaters (Adopted 9/16/99)
Rule 353 Adhesives and Sealants (Adopted 8/19/99)
Rule 808 New Source Review for Major Sources of Hazardous Air Pollutants (Adopted 5/20/99)

B. After review of the rules submitted by Ventura County APCD against the criteria set forth above and in 40 CFR part 55, EPA proposing to make the following new rule applicable to OCS sources for which the Ventura County APCD is designated as the COA and to delete two obsolete rules:

1. *The following new rule was submitted:*

Rule 74.11.1 Large Water Heaters and Small Boilers (Adopted 9/14/99)

2. *The following obsolete rules are being deleted from 40 CFR Part 55:*

Appendix II–B Best Available Control Technology Table
Appendix IV–A Soap Bubble Tests

III. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, Regulatory Planning and Review.

B. Executive Order 13132

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612, Federalism and 12875, Enhancing the Intergovernmental Partnership. Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This rule is not subject to E.O. 13045 because it is does not involve decisions intended to mitigate environmental health or safety risks.

[2] Each COA which has been delegated the authority to implement and enforce part 55, will use its administrative and procedural rules as onshore. However, in those instances where EPA has not delegated authority to implement and enforce part 55, EPA will use its own administrative and procedural requirements to implement the substantive requirements. 40 CFR 55.14 (c)(4).

D. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.*, v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 55

Environmental protection, Administrative practice and procedures, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Nitrogen oxides, Outer Continental Shelf, Ozone, Particulate matter, Permits, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: November 5, 1999.

Laura Yoshii,

Deputy Regional Administrator, Region IX.

Title 40 of the Code of Federal Regulations, part 55, is proposed to be amended as follows:

PART 55—[AMENDED]

1. The authority citation for part 55 continues to read as follows:

Authority: Section 328 of the Clean Air Act (42 U.S.C. § 7401 *et seq.*) as amended by Public Law 101–549.

2. Section 55.14 is proposed to be amended by revising paragraphs (e)(3)(ii)(F) and (e)(3)(ii)(H) to read as follows:

§ 55.14 Requirements that apply to OCS sources located within 25 miles of states seaward boundaries, by state.

* * * * *

(e) * * *

(3) * * *

(ii) * * *

(F) *Santa Barbara County Air Pollution Control District Requirements Applicable to OCS Sources.*

* * * * *

(H) *Ventura County Air Pollution Control District Requirements Applicable to OCS Sources.*

* * * * *

3. Appendix A to CFR Part 55 is proposed to be amended by revising paragraph (b)(6) and (8) under the heading ''California'' to read as follows:

Appendix A to 40 CFR Part 55—Listing of State and Local Requirements Incorporated by Reference Into Part 55, by State

* * * * *

California

* * * * *

(b) Local requirements.

* * * * *

(6) The following requirements are contained in *Santa Barbara County Air Pollution Control District Requirements Applicable to OCS Sources:*

Rule 102 Definitions (Adopted 5/20/99)
Rule 103 Severability (Adopted 10/23/78)
Rule 106 Notice to Comply for Minor Violations (Adopted 7/15/99)
Rule 201 Permits Required (Adopted 4/17/97)
Rule 202 Exemptions to Rule 201 (Adopted 4/17/97)
Rule 203 Transfer (Adopted 4/17/97)
Rule 204 Applications (Adopted 4/17/97)
Rule 205 Standards for Granting Applications (Adopted 4/17/97)
Rule 206 Conditional Approval of Authority to Construct or Permit to Operate (Adopted 10/15/91)
Rule 207 Denial of Application (Adopted 10/23/78)
Rule 210 Fees (Adopted 4/17/97)
Rule 212 Emission Statements (Adopted 10/20/92)
Rule 301 Circumvention (Adopted 10/23/78)
Rule 302 Visible Emissions (Adopted 10/23/78)
Rule 304 Particulate Matter-Northern Zone (Adopted 10/23/78)
Rule 305 Particulate Matter Concentration-Southern Zone (Adopted 10/23/78)
Rule 306 Dust and Fumes-Northern Zone (Adopted 10/23/78)
Rule 307 Particulate Matter Emission Weight Rate-Southern Zone (Adopted 10/23/78)

Rule 308 Incinerator Burning (Adopted 10/23/78)
Rule 309 Specific Contaminants (Adopted 10/23/78)
Rule 310 Odorous Organic Sulfides (Adopted 10/23/78)
Rule 311 Sulfur Content of Fuels (Adopted 10/23/78)
Rule 312 Open Fires (Adopted 10/2/90)
Rule 316 Storage and Transfer of Gasoline (Adopted 4/17/97)
Rule 317 Organic Solvents (Adopted 10/23/78)
Rule 318 Vacuum Producing Devices or Systems-Southern Zone (Adopted 10/23/78)
Rule 321 Solvent Cleaning Operations (Adopted 9/18/97)
Rule 322 Metal Surface Coating Thinner and Reducer (Adopted 10/23/78)
Rule 323 Architectural Coatings (Adopted 7/18/96)
Rule 324 Disposal and Evaporation of Solvents (Adopted 10/23/78)
Rule 325 Crude Oil Production and Separation (Adopted 1/25/94)
Rule 326 Storage of Reactive Organic Liquid Compounds (Adopted 12/14/93)
Rule 327 Organic Liquid Cargo Tank Vessel Loading (Adopted 12/16/85)
Rule 328 Continuous Emission Monitoring (Adopted 10/23/78)
Rule 330 Surface Coating of Miscellaneous Metal Parts and Products (Adopted 4/21/95)
Rule 331 Fugitive Emissions Inspection and Maintenance (Adopted 12/10/91)
Rule 332 Petroleum Refinery Vacuum Producing Systems, Wastewater Separators and Process Turnarounds (Adopted 6/11/79)
Rule 333 Control of Emissions from Reciprocating Internal Combustion Engines (Adopted 4/17/97)
Rule 342 Control of Oxides of Nitrogen (NOx) from Boilers, Steam Generators and Process Heaters) (Adopted 4/17/97)
Rule 343 Petroleum Storage Tank Degassing (Adopted 12/14/93)
Rule 344 Petroleum Sumps, Pits, and Well Cellars (Adopted 11/10/94)
Rule 352 Natural Gas-Fired Fan-Type Central Furnaces and Residential Water Heaters (Adopted 9/16/99)
Rule 353 Adhesives and Sealants (Adopted 8/19/99)
Rule 359 Flares and Thermal Oxidizers (6/28/94)
Rule 370 Potential to Emit—Limitations for Part 70 Sources (Adopted 6/15/95)
Rule 505 Breakdown Conditions Sections A.,B.1,. and D. only (Adopted 10/23/78)
Rule 603 Emergency Episode Plans (Adopted 6/15/81)
Rule 702 General Conformity (Adopted 10/20/94)
Rule 801 New Source Review (Adopted 4/17/97)
Rule 802 Nonattainment Review (Adopted 4/17/97)
Rule 803 Prevention of Significant Deterioration (Adopted 4/17/97)
Rule 804 Emission Offsets (Adopted 4/17/97)
Rule 805 Air Quality Impact Analysis and Modeling (Adopted 4/17/97)
Rule 808 New Source Review for Major Sources of Hazardous Air Pollutants (Adopted 5/20/99)
Rule 1301 Part 70 Operating Permits—General Information (Adopted 4/17/97)
Rule 1302 Part 70 Operating Permits—Permit Application (Adopted 11/09/93)
Rule 1303 Part 70 Operating Permits—Permits (Adopted 11/09/93)
Rule 1304 Part 70 Operating Permits—Issuance, Renewal, Modification and Reopening (Adopted 11/09/93)
Rule 1305 Part 70 Operating Permits—Enforcement (Adopted 11/09/93)

* * * * *

(8) The following requirements are contained in *Ventura County Air Pollution Control District Requirements Applicable to OCS Sources*:

Rule 2 Definitions (Adopted 11/10/98)
Rule 5 Effective Date (Adopted 5/23/72)
Rule 6 Severability (Adopted 11/21/78)
Rule 7 Zone Boundaries (Adopted 6/14/77)
Rule 10 Permits Required (Adopted 6/13/95)
Rule 11 Definition for Regulation II (Adopted 6/13/95)
Rule 12 Application for Permits (Adopted 6/13/95)
Rule 13 Action on Applications for an Authority to Construct (Adopted 6/13/95)
Rule 14 Action on Applications for a Permit to Operate (Adopted 6/13/95)
Rule 15.1 Sampling and Testing Facilities (Adopted 10/12/93)
Rule 16 BACT Certification (Adopted 6/13/95)
Rule 19 Posting of Permits (Adopted 5/23/72)
Rule 20 Transfer of Permit (Adopted 5/23/72)
Rule 23 Exemptions from Permits (Adopted 7/9/96)
Rule 24 Source Recordkeeping, Reporting, and Emission Statements (Adopted 9/15/92)
Rule 26 New Source Review (Adopted 10/22/91)
Rule 26.1 New Source Review—Definitions (Adopted 1/13/98)
Rule 26.2 New Source Review—Requirements (Adopted 1/13/98)
Rule 26.3 New Source Review—Exemptions (Adopted 1/13/98)
Rule 26.6 New Source Review—Calculations (Adopted 1/13/98)
Rule 26.8 New Source Review—Permit To Operate (Adopted 10/22/91)
Rule 26.10 New Source Review—PSD (Adopted 1/13/98)
Rule 28 Revocation of Permits (Adopted 7/18/72)
Rule 29 Conditions on Permits (Adopted 10/22/91)
Rule 30 Permit Renewal (Adopted 5/30/89)
Rule 32 Breakdown Conditions: Emergency Variances, A., B.1., and D. only. (Adopted 2/20/79)
Rule 33 Part 70 Permits—General (Adopted 10/12/93)
Rule 33.1 Part 70 Permits—Definitions (Adopted 10/12/93)
Rule 33.2 Part 70 Permits—Application Contents (Adopted 10/12/93)
Rule 33.3 Part 70 Permits—Permit Content (Adopted 10/12/93)
Rule 33.4 Part 70 Permits—Operational Flexibility (Adopted 10/12/93)
Rule 33.5 Part 70 Permits—Time frames for Applications, Review and Issuance (Adopted 10/12/93)
Rule 33.6 Part 70 Permits—Permit Term and Permit Reissuance (Adopted 10/12/93)
Rule 33.7 Part 70 Permits—Notification (Adopted 10/12/93)
Rule 33.8 Part 70 Permits—Reopening of Permits (Adopted 10/12/93)
Rule 33.9 Part 70 Permits—Compliance Provisions (Adopted 10/12/93)
Rule 33.10 Part 70 Permits—General Part 70 Permits (Adopted 10/12/93)
Rule 34 Acid Deposition Control (Adopted 3/14/95)
Rule 35 Elective Emission Limits (Adopted 11/12/96)
Rule 36 New Source Review—Hazardous Air Pollutants (Adopted 10/6/98)
Rule 42 Permit Fees (Adopted 6/22/99)
Rule 44 Exemption Evaluation Fee (Adopted 9/10/96)
Rule 45 Plan Fees (Adopted 6/19/90)
Rule 47 Source Test, Emission Monitor, and Call-Back Fees (Adopted 6/22/99)
Rule 45.2 Asbestos Removal Fees (Adopted 8/4/92)
Rule 50 Opacity (Adopted 2/20/79)
Rule 52 Particulate Matter-Concentration (Adopted 5/23/72)
Rule 53 Particulate Matter-Process Weight (Adopted 7/18/72)
Rule 54 Sulfur Compounds (Adopted 6/14/94)
Rule 56 Open Fires (Adopted 3/29/94)
Rule 57 Combustion Contaminants-Specific (Adopted 6/14/77)
Rule 60 New Non-Mobile Equipment-Sulfur Dioxide, Nitrogen Oxides, and Particulate Matter (Adopted 7/8/72)
Rule 62.7 Asbestos—Demolition and Renovation (Adopted 6/16/92)
Rule 63 Separation and Combination of Emissions (Adopted 11/21/78)
Rule 64 Sulfur Content of Fuels (Adopted 4/13/99)
Rule 67 Vacuum Producing Devices (Adopted 7/5/83)
Rule 68 Carbon Monoxide (Adopted 6/14/77)
Rule 71 Crude Oil and Reactive Organic Compound Liquids (Adopted 12/13/94)
Rule 71.1 Crude Oil Production and Separation (Adopted 6/16/92)
Rule 71.2 Storage of Reactive Organic Compound Liquids (Adopted 9/26/89)
Rule 71.3 Transfer of Reactive Organic Compound Liquids (Adopted 6/16/92)
Rule 71.4 Petroleum Sumps, Pits, Ponds, and Well Cellars (Adopted 6/8/93)
Rule 71.5 Glycol Dehydrators (Adopted 12/13/94)
Rule 72 New Source Performance Standards (NSPS) (Adopted 9/10/96)
Rule 74 Specific Source Standards (Adopted 7/6/76)
Rule 74.1 Abrasive Blasting (Adopted 11/12/91)
Rule 74.2 Architectural Coatings (Adopted 08/11/92)

Rule 74.6 Surface Cleaning and Degreasing (Adopted 11/10/98)
Rule 74.6.1 Cold Cleaning Operations (Adopted 7/9/96)
Rule 74.6.2 Batch Loaded Vapor Degreasing Operations (Adopted 7/9/96)
Rule 74.7 Fugitive Emissions of Reactive Organic Compounds at Petroleum Refineries and Chemical Plants (Adopted 10/10/95)
Rule 74.8 Refinery Vacuum Producing Systems, Waste-water Separators and Process Turnarounds (Adopted 7/5/83)
Rule 74.9 Stationary Internal Combustion Engines (Adopted 12/21/93)
Rule 74.10 Components at Crude Oil Production Facilities and Natural Gas Production and Processing Facilities (Adopted 3/10/95)
Rule 74.11 Natural Gas-Fired Residential Water Heaters-Control of NO_X (Adopted 4/9/85)
Rule 74.11.1 Large Water Heaters and Small Boilers (Adopted 9/14/99)
Rule 74.12 Surface Coating of Metal Parts and Products (Adopted 9/10/96)
Rule 74.15 Boilers, Steam Generators and Process Heaters (5MM BTUs and greater) (Adopted 11/8/94)
Rule 74.15.1 Boilers, Steam Generators and Process Heaters (1–5MM BTUs)(Adopted 6/13/95)
Rule 74.16 Oil Field Drilling Operations (Adopted 1/8/91)
Rule 74.20 Adhesives and Sealants (Adopted 1/14/97)
Rule 74.23 Stationary Gas Turbines (Adopted 10/10/95)
Rule 74.24 Marine Coating Operations (Adopted 9/10/96)
Rule 74.24.1 Pleasure Craft Coating and Commercial Boatyard Operations (Adopted 11/10/98)
Rule 74.26 Crude Oil Storage Tank Degassing Operations (Adopted 11/8/94)
Rule 74.27 Gasoline and ROC Liquid Storage Tank Degassing Operations (Adopted 11/8/94)
Rule 74.28 Asphalt Roofing Operations (Adopted 5/10/94)
Rule 74.30 Wood Products Coatings (Adopted 9/10/96)
Rule 75 Circumvention (Adopted 11/27/78)
Rule 100 Analytical Methods (Adopted 7/18/72)
Rule 101 Sampling and Testing Facilities (Adopted 5/23/72)
Rule 102 Source Tests (Adopted 11/21/78)
Rule 103 Continuous Monitoring Systems (Adopted 2/9/99)
Rule 154 Stage 1 Episode Actions (Adopted 9/17/91)
Rule 155 Stage 2 Episode Actions (Adopted 9/17/91)
Rule 156 Stage 3 Episode Actions (Adopted 9/17/91)
Rule 158 Source Abatement Plans (Adopted 9/17/91)
Rule 159 Traffic Abatement Procedures (Adopted 9/17/91)
Rule 220 General Conformity (Adopted 5/9/95)

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[FR Doc. 99–30236 Filed 11–18–99; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPPTS–50637; FRL–6385–8]

RIN 2070–AB27

Proposed Revocation of Significant New Use Rules for Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revoke significant new use rules (SNURs) for 2 substances promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) based on new data. Based on the new data the Agency no longer finds that activities not described in the corresponding TSCA section 5(e) consent order for these chemical substances may result in significant changes in human or environmental exposure.

DATES: Comments, identified by docket control number OPPTS–50637, must be received on or before December 20, 1999.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–50637 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Joe Carra, Deputy Director, Office of Pollution Prevention and Toxics (7401), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone numbers: (202) 554–1404 and TDD: (202) 554–0551; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: James Alwood, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (202) 260–1857; e-mail address: alwood.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances contained in this proposed rule. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Chemical manufacturers	325	Manufacturers, importers, processors, and users of chemicals
Petroleum and coal product industries	324	Manufacturers, importers, processors, and users of chemicals

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action applies to certain entities. To determine whether you or your business is affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**-Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPPTS–50637. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in

those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B–607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260–7099.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–50637 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: OPPT Document Control Office (DCO) in East Tower Rm. G–099, Waterside Mall, 401 M St., SW., Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 260–7093.

3. *Electronically.* You may submit your comments electronically by e-mail to: ''oppt.ncic@epa.gov,'' or mail your computer disk to the address identified above. Do not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard disks in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPPTS–50637. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI Information That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the technical person identified under ''FOR FURTHER INFORMATION CONTACT.''

E. What Should I Consider as I Prepare My Comments for EPA?

We invite you to provide your views on the various options we propose, new approaches we have not considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider during the development of the final action. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the proposed rule.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. What Action is the Agency Taking?

In the **Federal Register** referenced for each substance, OPPTS–50591C, July 22, 1992, 57 FR 32441 and OPPTS–50615, May 27, 1994, 59 FR 27474 establishing significant new uses for the substances, EPA issued a SNUR. Because of additional data EPA has received for these substances, EPA is proposing to revoke the significant new use and recordkeeping requirements for the following chemical substances under 40 CFR part 721, subpart E. In this unit, EPA provides a brief description for the substances, including its premanufacture notice (PMN) number, chemical name (generic name if the specific name is claimed as CBI), CAS number (if assigned), basis for the revocation of the TSCA section 5(e) consent order for the substance, and the CFR citation removed in the regulatory text section of this proposed rule. Further background information for the substances is contained in Unit I.B.2 of this document.

PMN Number P–88–1763

Chemical name: Ethane, 2-chloro-1,1,1,2-tetrafluoro-.
CAS number: 2837–89–0.
Federal Register *publication date and reference:* July 22, 1992 (57 FR 32441).
Docket number: OPPTS–50591C.
Basis for revocation of SNUR: EPA received and evaluated the following toxicity testing. A chronic inhalation study in rats showed no significant effects at 2,000, 10,000 or 50,000 parts per million (ppm). For a 90-day inhalation study in mice, the No Observed Adverse Effect Level (NOAEL) was 15,000 ppm with reduced response to sound at 50,000 ppm. In a 90-day inhalation study in rats, the NOAEL was 5,000 ppm (3,200 mg/kg/day) for males based on lower serum triglyceride levels and decreased arousal at 15,000 ppm; the NOAEL for females was 15,000 ppm. In a 28-day inhalation study in rats, the PMN substance caused lethargy at 50,000 ppm. In a developmental toxicity study in rats by inhalation, the only effects were reduced maternal weight gain and reduced response to sound at 50,000 ppm. There were no fetal effects. In a rabbit development toxicity study (inhalation), there was reduced activity in maternal animals at 50,000 ppm. In addition, a cardiac sensitization study in dogs, showed effects at 25,000 ppm but not at 10,000 ppm. The substance was negative in the Ames assay and the mouse micronucleus assay. Based on the assessment of these test data, EPA determined that it could no longer support an unreasonable risk finding under section 5(e) of TSCA and has revoked the consent order. EPA can no longer make the finding that activities not described in the TSCA section 5(e) consent order may result in significant changes in human exposure.
CFR citation: 40 CFR 721.3180.

PMN Number P–93–1235

Chemical name: 2-Propenoic acid 3-(trimethoxysilyl) propyl ester.
CAS number: Not available.
Federal Register *publication date and reference:* May 27, 1994 (59 FR 27474).

Docket number: OPPTS–50615.
Basis for revocation of SNUR: Based on short term studies on a series of acrylate substances and long term dermal bioassays on triethylene glycol diacrylate and triethylene glycol dimethacrylate, EPA no longer supports a carcinogenicity concern for this substance. Based on that assessment, EPA can no longer make the finding that activities not described in the PMN may result in significant changes in human exposure.
CFR citation: 40 CFR 721.8654.

B. What is the Agency's Authority for Taking this Action?

During review of the PMNs submitted for the chemical substances that are the subject of this proposed revocation, EPA concluded that regulation was warranted based on available information that indicated activities not described in the TSCA section 5(e) consent order or the PMN might result in significant changes in human or environmental exposure as described in section 5(a)(2) of TSCA. Based on these findings, SNURs were promulgated.

EPA has revoked the TSCA section 5(e) consent order that is the basis for one of the SNURs and no longer finds that activities other than those described in the TSCA section 5(e) consent order or the PMN may result in significant changes in human or environmental exposure. The revocation of SNUR provisions for these substances is consistent with the findings set forth in the preamble to the proposed revocation of each individual SNUR.

Therefore, EPA is proposing to revoke the SNUR provisions for these chemical substances. When this revocation becomes final, EPA will no longer require notice of intent to manufacture, import, or process these substances. In addition, export notification under section 12(b) of TSCA will no longer be required.

III. Regulatory Assessment Requirements

This proposed rule revokes or eliminates an existing regulatory requirement and does not contain any new or amended requirements. As such, the Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993).

Since this proposed rule does not impose any requirements, it does not contain any information collections subject to approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or require any other action under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

Nor does it require any prior consultation as specified by Executive Order 12875, entitled ''Enhancing the Intergovernmental Partnership'' (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994) or require OMB review in accordance with Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997).

On August 4, 1999, President Clinton issued a new executive order on Federalism, Executive Order 13132 (64 FR 43255, August 10, 1999), which will take effect on November 2, 1999. In the interim, the current Executive Order 12612 (52 FR 41685, October 30, 1987) on Federalism still applies. This proposed rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612.

In addition, pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency has determined that SNUR revocations, which eliminate requirements without imposing any new ones, have no adverse economic impacts. The Agency's generic certification for SNUR revocations appears on June 2, 1997 (62 FR 29684) (FRL–5597–1) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: November 1, 1999.

Ward Penberthy,

Acting Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721—[AMENDED]

1.The authority citation for part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625 (c).

§§ 721.3180, 721.8654 [Removed]

2. By removing §§ 721.3180 and 721.8654.

[FR Doc. 99–30241 Filed 11–18–99; 8:45 am]
BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter I

[WT Docket 96–198; FCC 99–181]

Access to Internet Telephony and Computer Based Equipment by Persons With Disabilities

AGENCY: Federal Communications Commission.

ACTION: Notice of inquiry.

SUMMARY: This document examines the need and legal basis for applying rules similar to those developed for telecommunications services and customer premise equipment pursuant to section 255 to internet telephony and computer based equipment that performs the same functions that customer premise equipment performs.

DATES: Comments are due January 13, 2000 and reply comments are due on February 14, 2000.

ADDRESSES: Office of the Secretary, Federal Communications Commission, 445 Twelfth Street S.W., Room TW–A325, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Ellen Blackler, Common Carrier Bureau. 202–418–0491.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's further Notice of Inquiry in WT Docket 96–198, adopted on July 14, 1999 and released on September 29, 1999. The full text of the Notice of Inquiry, including Commissioners' statements, is available for inspection and copying during normal business hours in the FCC Reference Center, 445 Twelfth Street, SW, Room CY–257, Washington, D.C. Alternate formats (computer diskette, large print, audio cassette and Braille) are available to persons with disabilities by contacting Martha Contee at (202) 418–0260 (voice), (202) 418–2555 (TTY), or at mcontee@fcc.gov. The Further Notice of Inquiry can be downloaded in WP or ASCII text at: http//www.fcc.gov/dtf/.

Summary of Further Notice of Inquiry

I. Overview

1. We are cognizant, in general, of the speed with which innovative next generation technologies are changing the way communications services are

offered to the public, and the challenges posed to the disability community by these new technologies if they are not accessible. We lack, however, knowledge of the specific characteristics of those changes, and the implications for accessibility for people with disabilities. Given the rapid evolution of communications and the pace of technological innovation, we need to ensure that as new services and networks are developed they are designed to provide access to persons with disabilities.

2. All paper filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 Twelfth Street S.W., Room TW–A325, Washington, DC 20554. Accordingly, we are issuing this Notice of Inquiry (NOI) to aid our understanding of the access issues presented by communications services and equipment not covered by the section 255 rules. Our goal is to take full advantage of the promise of new technology, not only to ensure that advancements do not leave people with disabilities behind, but also to harness the power of innovation to break down the accessibility barriers we face today and prevent their emergence tomorrow. While we are interested in all aspects of communications technology that may present accessibility issues, we specifically request information on two types, Internet telephony and computer-based equipment that replicates telecommunications functionality.

II. Internet Telephony

3. Internet Protocol telephony (''Internet'' or ''IP'' telephony) services enable real-time voice transmission using the Internet Protocol (IP), a packet-switched communications protocol. The services can be provided in two basic ways: computer-to-computer IP telephony conducted through special software and hardware at an end user's premises; or phone-to-phone IP telephony conducted through ''gateways'' that enable applications originating and/or terminating on the public switched network. Phone-to-phone IP telephony is provided through computer gateways that allow end users to make and receive calls using their traditional telephones. Gateways translate the circuit-switched voice signal into IP packets, and vice versa, and perform associated signalling, control, and address translation functions. The voice communications can then be transmitted along with other data on the ''public'' Internet, or can be routed through intranets or other private data networks for improved performance.

4. We ask commenters to provide any further information as to the extent to which phone-to-phone IP telephony services might impact the disability community, and the steps, we should take to address any adverse impacts in order to fulfill the goals of section 255, or otherwise promote the accessibility of this technology. Commenting parties should offer specific suggestions as to the appropriate role for the Commission in guaranteeing access and the statutory basis for that role. For example, commenters should address ways in which phone to phone IP telephony may be interpreted as falling within the purview of section 255. Commenters should provide specific definitions of the services or equipment to which the statute might apply, and the appropriate means of limiting its application to only those services and equipment. Commenters should address the ways, if any, in which industry bodies can ensure access without regulatory action. Commenters should also describe the specific access issues or experiences that might arise with IP telephony. For example, will TTY tones be adequately transmitted in a packet-switched environment? Will persons with speech disabilities whose speech patterns and voice outputs from alternative and augmentative communications devices may fall outside of traditional voice patterns, face additional communications barriers with packetized voice services?

5. We further ask commenters to address what efforts manufacturers of equipment that performs phone-to-phone IP telephony functions and providers of phone-to-phone IP telephony services are currently making to ensure that such equipment and services are accessible. What improvements in accessibility may be possible through the use of phone-to-phone IP telephony? Are there natural opportunities for incorporating accessibility into IP telephony? Can greater accessibility be achieved if requirements are adopted early in the development of IP Telephony? Is it possible that greater levels of accessibility will be readily achievable with IP telephony than conventional telephony? How will compatibility with assistive technology affect the use of IP telephony?

6. Commenters should also address the extent to which IP telephony is now, or soon will be, an effective substitute for conventional circuit-switched telephony. As Internet usage grows, phone-to-phone voice IP telephony may be used with increasing frequency as an alternative to more traditional telephone service. How extensive is Internet telephony usage today? What is the projected usage of Internet telephony in the near future? What is the projected use of various kinds of IP telephony by persons with disabilities?

7. Commenters are asked to describe differences in characteristics between computer-based and phone-based IP telephony, and whether such differences merit different treatment by the Commission. Given the rapid pace of technological change in the telecommunications marketplace, we also ask commenters to apprise us of any new technologies that may impact the availability of accessible services and equipment.

III. Computer Based Equipment

8. We also seek comment on another aspect of the network of the future—the movement of telecommunications and information service functions from the network, or the terminal equipment which connects directly to the network, into computer equipment which does not connect to the network directly. This computer hardware and software is not typically regarded as CPE, but may, in fact, deliver the same functions we seek to make accessible. For instance, voicemail, interactive menus, or phone-to-phone IP telephony in current network topologies can reside in equipment located on the service provider's premises, but such functionalities are also available in several forms to end users on their own premises. For example, voicemail can be purchased from a carrier, can be provided via software and a private branch exchange (PBX), or can be provided through a computer that connects with the PBX, but is not generally regarded as part of the PBX. It is this latter application as to which we seek comment.

9. These software applications shift the potential for accessibility solutions from the core of the network to the end user's premises. We therefore ask commenters to address whether equipment that provides these capabilities, but which does not connect directly into the public network (or otherwise directly receive the transmission of the telecommunications), should be considered to be CPE subject to the requirements of section 255. We note, for example, that this Order does not currently reach a software telephone or the personal computer on which it resides, even though it performs the same functions as the traditional telephone.

10. We ask commenters to address the need to include this computer-based equipment as CPE or otherwise apply

the provisions of these rules to that equipment in order to ensure access. We also ask commenters to address whether failure to bring such equipment within the scope of section 255 would create a serious gap in coverage that would interfere with our ability to effectively implement its provisions. Commenters should offer suggestions as to the appropriate role for the Commission in ensuring access for this kind of equipment and the statutory basis for that role. We also ask about the potential for this kind of equipment for improving accessibility and its compatibility with assistive technology. Is it possible that greater levels of accessibility will be readily achievable if this kind of equipment has accessibility requirements?

IV. Procedural Matters

11. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, interested parties may file comments as follows: Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies.

12. Comments filed through the ECFS can be sent as an electronic file via the Internet to http://www.fcc.gov/e-file/ecfs.html. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic copy by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to *ecfs@fcc.gov*, and should include the following words in the body of the message: ''get form <your email address>.'' A sample form and directions will be sent in reply.

13. Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number. All paper filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 Twelfth Street S.W., Room TW–A325, Washington, DC 20554.

14. Parties who choose to file by paper should also submit their comments on diskette to Al McCloud, Network Services Division, Common Carrier Bureau, Federal Communications Commission, 445 Twelfth Street SW, Room 6–A423, Washington, DC 20554. Such a submission should be on a 3.5 inch diskette formatted in an IBM-compatible format using WordPerfect 5.1 for Windows or a compatible software. The diskette should be accompanied by a cover letter and should be submitted in read-only mode. The diskette should be clearly labeled with the commenter's name, proceeding, including the lead docket number in the proceeding (CC Docket No. 96–198), type of pleading (comment or reply comment), date of submission, and the name of the electronic file on the diskette. The label should also include the following phrase (Disk Copy—Not an Original.) Each diskette should contain only one party's pleadings, preferably in a single electronic file. In addition, commenters should send diskette copies to the Commission's copy contractor, International Transcription Service, Inc., 1231 20th St. NW, Washington, DC 20037.

15. Alternate formats (computer diskette, large print, audio cassette and Braille) are available to persons with disabilities by contacting Martha Contee at (202)418–0260 (voice), (202)418–2555 (TTY), or at mcontee@fcc.gov. The Further Notice of Inquiry can be downloaded in Wp or ASCII test at: http://www.fcc.gov/dtf/.

V. Ordering Clauses

16. The authority contained in sections 1, 2, 4, 201(b), 208, 251(a)(2), 255, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154, 201(b), 208, 251(a)(2), 255, 303(r), this Notice of Inquiry IS ADOPTED and comments ARE REQUESTED.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 99–30092 Filed 11–18–99; 8:45 am]

BILLING CODE 6712–01–U

DEPARTMENT OF TRANSPORTATION

49 CFR Ch. I

Office of the Secretary

[Docket OST–1996–1880]

Nondiscrimination on the Basis of Handicap in Air Travel

AGENCY: Office of the Secretary, DOT.

ACTION: Notice of public meeting.

SUMMARY: DOT is convening a public meeting to discuss whether the Department should commence a rulemaking to require certain additional accommodations for hearing-impaired passengers under the Air Carrier Access Act of 1986. This notice announces the date, time, location, and procedures for the public meeting.

DATES: The public meeting is scheduled for November 30, 1999, from 9 a.m. to 5 p.m. EST.

ADDRESSES: The public meeting will be held in Room 2101 at the Department of Transportation, 400 Seventh Street, SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Sophy Chen, Office of the Assistant General Counsel for Regulation and Enforcement, telephone number (202) 366–9353 or via email at sophy.chen@ost.dot.gov; or Robert Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, telephone number (202) 366–9310 (voice) or (202) 755–7687 (TDD), or via email at bob.ashby@ost.dot.gov.

SUPPLEMENTARY INFORMATION:

Background

In a November 1996 notice of proposed rulemaking (NPRM), the Department proposed to amend the Department's Air Carrier Access Act (ACAA) rules regarding seating accommodations for individuals with disabilities and the stowage of collapsible electric wheelchairs (61 FR 56481; November 1, 1996). In that NPRM, the Department also requested comments on the following four suggestions the Department had received regarding accommodations for persons with hearing impairments: (1) Captioning of video material (*e.g.*, movies and other entertainment features) shown on the aircraft; (2) making telecommunications devices for the deaf (TDDs) available where air phone service is provided to other passengers; (3) providing assistive listening technology for public address announcements in the aircraft; and (4) providing electronic message or assistive listening technology in gate areas. The Department sought comments on the need for such accommodations, as well as their technical feasibility and cost.

The Department received several comments, which are available in Docket OST–1996–1880. The Department's dockets are available at DOT Headquarters, 400 Seventh Street, SW., Washington, DC, in Room PL–104 and can also be accessed at the Department's Docket Management

System Internet site (http://dms.dot.gov). In the preamble for the final rule that resulted from the November 1996 rulemaking, however, the Department deferred decision on whether to require these accommodations for hearing-impaired passengers. At this time, the Department seeks to reopen discussion about these suggestions.

Meeting Procedures

1. To reserve a seat or to ensure that you have the opportunity to speak, please contact Sophy Chen (see information under **FOR FURTHER INFORMATION CONTACT**) as soon as possible. The meeting is otherwise open for observation without prior arrangement. Seating, however, will be restricted by room size and will be available on a first-come, first-served basis.

2. The meeting will be structured so that a balanced group of interested parties are the primary participants. However, opportunities for anyone in attendance to speak will be made available as well. For scheduling purposes, anyone wishing to make a short presentation highlighting technologies that are relevant to making air travel accessible for hearing-impaired individuals are encouraged to contact Sophy Chen (see information under **FOR FURTHER INFORMATION CONTACT**) as soon as possible.

3. The purpose of the meeting is to solicit views and more complete information on the need, feasibility, and cost of the suggested accommodations for hearing-impaired air travelers. The meeting will be conducted, therefore, in an informal and non-adversarial manner. No individual will be subject to cross-examination by any other participant. Panel members may, however, ask questions to clarify statements and to ensure a complete and accurate record.

Issued in Washington, DC on November 10, 1999.

Rosalind A. Knapp,

Deputy General Counsel.

[FR Doc. 99–30291 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–62–P

Notices

Federal Register
Vol. 64, No. 223
Friday, November 19, 1999

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Federal Invention Available for Licensing and Intent To Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of availability and intent.

SUMMARY: Notice is hereby given that a Federally owned invention U.S. Patent No. 5,725,863 (S.N. 07/756,346 filed September 6, 1991, entitled ''Polypeptides Useful in Prevention of Chlamydia Infection'' is available for licensing and the U.S. Department of Agriculture, Agricultural Research Service, intends to grant to BTG International Inc., of Gulph Mills, Pennsylvania, an exclusive license to Serial No. 07/756,346.

DATES: Comments must be received on or before February 17, 2000.

ADDRESSES: Send comments to: USDA, ARS, Office of Technology Transfer, 5601 Sunnyside Avenue, Room 4–1158, Beltsville, Maryland 20705–5131.

FOR FURTHER INFORMATION CONTACT: June Blalock of the Office of Technology Transfer at the Beltsville address given above; telephone: 301–504–5989.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights to this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as BTG International Inc., has submitted a complete and sufficient application for a license. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within ninety (90) days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Richard M. Parry, Jr.,

Assistant Administrator.

[FR Doc. 99–30220 Filed 11–18–99; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Federal Invention Available for Licensing and Intent To Grant Co-Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of availability and intent.

SUMMARY: Notice is hereby given that a Federally owned invention U.S. Patent No. 5,591,434 issued on January 7, 1997, entitled ''DNA Sequence Encoding Surface Protein of Cryptosporidium Parvum'' is available for licensing and the U.S. Department of Agriculture, Agricultural Research Service, intends to grant to Merial Limited of Athens, Georgia, and Fort Dodge Animal Health Corporation of Overland Park, Kansas, co-exclusive license to S.N. 08/229,393.

DATES: Comments must be received on or before February 17, 2000.

ADDRESSES: Send comments to: USDA, ARS, Office of Technology Transfer, 5601 Sunnyside Avenue, Beltsville, Maryland 20705–5131.

FOR FURTHER INFORMATION CONTACT: June Blalock of the Office of Technology Transfer at the Beltsville address given above; telephone: 301–504–5989.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights to this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as Merial Limited and Fort Dodge Animal Health Corporation have submitted complete and sufficient applications for a license. The prospective co-exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective co-exclusive license may be granted unless, within ninety (90) days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Richard M. Parry, Jr.,

Assistant Administrator.

[FR Doc. 99–30221 Filed 11–18–99; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 99–054N]

National Advisory Committee on Microbiological Criteria for Foods

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) will hold public meetings on December 8–10, 1999. On December 8–9, 1999, NACMCF will discuss recent research and other information related to performance criteria for fresh juice, in particular citrus juices, and on December 10, 1999, the Food Safety Inspection Service (FSIS) will present issues related to the risk assessment models under development to examine the relationship between *Escherichia coli* O157:H7 in ground beef and human health. The sponsoring agencies invite comments on issues related to these meetings.

DATES: The full committee will meet on Wednesday, Thursday, and Friday, December 8–10, 1999, beginning at 8 a.m.

ADDRESSES: All meetings will be held at the Doyle Hotel, Doyle Ballroom, 1500 New Hampshire Avenue (Dupont Circle), Washington, DC 20036, telephone (202) 483–6000. Submit one original and two copies of written comments on the risk assessment models to the FSIS Docket Clerk, Docket #99–054N, Room 102, Cotton Annex Building, 300 12th Street, SW., Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Persons wishing to register for the meeting or submit comments on fresh citrus juice should, by December 1, 1999, contact Ms. Catherine M. DeRoever, telephone (202) 205–4251,

fax (202) 205–4970, or e-mail cderoeve@bangate.fda.gov. Persons requiring a sign language interpreter or other special accommodations should notify Ms. DeRoever (fax number above) by December 1, 1999.

SUPPLEMENTARY INFORMATION:

Background

The NACMCF provides advice and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services regarding the microbiological safety of foods. The Committee also provides advice to the Departments of Commerce and Defense. Dr. I. Kaye Wachsmuth, Deputy Administrator, Office of Public Health and Science, FSIS, is the Committee Chair.

Additional Public Notification

Public meetings generally are designed to provide information and receive public comments on issues that may lead to new or revised agency regulations or instructions. Public involvement in all segments of rulemaking and policy development are important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this public meeting and are informed about the mechanism for providing their comments, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update.

FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at *http://www.fsis.usda.gov.* The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/ stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

Done at Washington, DC, on November 15, 1999.

Thomas J. Billy,

Administrator.

[FR Doc. 99–30222 Filed 11–18–99; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 99–053N]

Technical Conference on the Sanitation Performance Standard Regulation

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: The Food Safety and Inspection Service (FSIS) is holding a public meeting on December 8–9, 1999, regarding FSIS's final rule, ''Sanitation Requirements for Official Meat and Poultry Establishments.'' At the meeting, participants will have an opportunity to discuss technical issues related to the sanitation performance standards. A steering committee made up of people from the Agency, industry, trade associations, and academia is developing the meeting agenda.

DATES: The public meeting will be held December 8–9, 1999, from 8:00 a.m. until 4:30 p.m. on the 8th and from 8:00 a.m until 2:30 p.m. on the 9th.

ADDRESSES: The public meeting will be held at the Double Tree Hotel, 1616 Dodge Street, Omaha, Nebraska 68102, Telephone (402) 346–7600. The meeting is open to the public on a space-available basis. To register for the meeting, contact Ms. Gaye Gerard of the FSIS's Technical Service Center on or before December 6, 1999, by Telephone (402) 221–7400, FAX (402) 221–7438, or e-mail *gaye.gerard@usda.gov.* Attendees who require a sign language interpreter or other special accommodation should contact Ms. Gerard at the above numbers.

FOR FURTHER INFORMATION CONTACT: Ms. Karlease Kelly, Technical Service Center, Office of Field Operations, Food Safety and Inspection Service, US Department of Agriculture, Suite 300, Landmark Center, 1299 Farnam Street, Omaha, Nebraska 68102, Telephone 402–221–7400, FAX 402–221–7421 or e-mail *karlease.kelly@usda.gov.*

SUPPLEMENTARY INFORMATION: On October 20, 1999, FSIS published the final rule, ''Sanitation Requirements for Official Meat and Poultry Establishments'' (64 FR 56400). This final rule revised the regulatory requirements concerning sanitation in official meat and poultry establishments. Specifically, the rule consolidated sanitation regulations into a single part applicable to both official meat and poultry establishments, eliminating unnecessary differences between the sanitation requirements for meat and poultry processing, and converting many of the highly prescriptive sanitation requirements to performance standards. The final rule will be effective on January 25, 2000.

The purpose of the meeting is to explain the intent of the regulation and to discuss technical issues related to the general sanitation provisions covered by the new regulations before they become effective.

Departmental Regulation 4300–4, ''Civil Rights Impact Analysis''

Pursuant to Department Regulation 4300–4, ''Civil Rights Impact Analysis,'' dated September 22, 1993, FSIS has considered the potential civil rights impact of this meeting on minorities, women, and persons with disabilities. This notice is designed to provide information to the public. Public involvement is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are made aware of this public meeting FSIS will announce the publication of this **Federal Register** notice in the FSIS Constitutent Update.

FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at *http://www.fsis.usda.gov.* The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** Notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/ stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information with a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Office of Congressional and Public Affairs, at (202) 720–5704.

Done at Washington, DC on: November 15, 1999.

Thomas J. Billy,

Administrator.

[FR Doc. 99–30223 Filed 11–18–99; 8:45 am]

BILLING CODE 3410–DM–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletion

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletion from Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete a service previously furnished by such agencies.

COMMENTS MUST BE RECEIVED ON OR BEFORE: December 20, 1999.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Gateway 3, Suite 310, 1215 Jefferson Davis Highway, Arlington, Virginia 22202–4302.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Additions

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities. I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action will result in authorizing small entities to furnish the commodities and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodities and services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodities

Canned Air Duster
6850–01–398–4797
7045–01–411–9794
7930–01–179–7236
NPA: Lighthouse for the Blind, St. Louis, Missouri

Services

Grounds Maintenance, Naval Air Station, New Orleans, Louisiana, NPA: Goodworks, Inc., New Orleans, Louisiana

Laundry Service

Seymour-Johnson Air Force Base, North Carolina
NPA: Chesapeake Service Systems, Inc., Chesapeake, Virginia

Deletion

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action will result in authorizing small entities to furnish the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the service proposed for deletion from the Procurement List.

The following service has been proposed for deletion from the Procurement List.

Administrative Services
General Services Administration, PBS
Laguna Niguel Field Offices
Laguna Niguel, California

Beverly L. Milkman,

Executive Director.

[FR Doc. 99–30286 Filed 11–18–99; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–357–007]

Carbon Steel Wire Rod From Argentina: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of antidumping duty administrative review.

SUMMARY: In response to a request from petitioners, the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on carbon steel wire rod from Argentina. The review covers one manufacturer/exporter of the subject merchandise to the United States, Acindar Industria Argentina de Aceros S.A. (''Acindar'') and the period November 1, 1997 through October 31, 1998.

We have preliminarily determined that respondent has made sales below normal value during the period of review. If these preliminary results are adopted in our final results of review, we will instruct the U.S. Customs Service to assess antidumping duties on entries subject to this review.

EFFECTIVE DATE: November 19, 1999.

FOR FURTHER INFORMATION CONTACT: Helen M. Kramer or Linda Ludwig, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone (202) 482–0405 or 482–3833, respectively.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the Trade and Tariff Act of 1930, as amended (the Act) are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act of 1994 (URAA). In addition, unless otherwise indicated, all references to the Department's regulations are to 19 CFR Part 351 (1998).

SUPPLEMENTARY INFORMATION:

Background

On November 23, 1984, the Department published an antidumping duty order on Carbon Steel Wire Rod from Argentina (49 FR 46180). The Department published a notice of ''Opportunity To Request

Administrative Review'' of the antidumping duty order for the 1997/1998 review period on November 12, 1998 (63 FR 63287). On November 30, 1998, the petitioners, Birmingham Steel Corporation, Cascade Steel Rolling Mills, Co-Steel Raritan, Connecticut Steel Corporation, GS Industries, Inc., Keystone Steel & Wire Company, North Star Steel Company, and Northwestern Steel & Wire Company, filed a request for review. We published a notice of initiation of this review on December 23, 1998 (63 FR 71091).

Due to the complexity of model match issues involved in this case, the Department extended the time limit for completion of the preliminary results until November 30, 1999, in accordance with section 751(a)(3)(A) of the Act. See 64 FR 55234 (October 12, 1999). The deadline for the final results of this review will continue to be 120 days after the date of publication of this notice. The Department is conducting this review in accordance with section 751 of the Act.

Scope of the Review

The product covered by this review is carbon steel wire rod. This merchandise is currently classifiable under HTS item numbers 7213.20.00, 7212.31.30, 72113.39.00, 721113.41.30, 7213.49.00, and 7213.50.00. These HTS subheadings are provided for convenience and U.S. Customs purposes. The written description of the scope of the proceeding is dispositive.

Verification

As provided in section 782(i)(3) of the Act, we verified sales information provided by Acindar at its headquarters in Buenos Aires and at its plant in Villa Constitución, Argentina, August 23 through 27, 1999, using standard verification procedures, including inspection of the manufacturing facilities, examination of relevant sales and financial records, and selection of original documentation containing relevant information. As a result of our findings at verification, we adjusted imputed credit expenses in both the U.S. and home markets and U.S. movement expenses. See ''Verification of Sales at Acindar Industria Argentina de Aceros S.A., Buenos Aires and Villa Constitución, Argentina, August 23–27, 1999,'' dated October 21, 1999, and ''Analysis of Sales by Acindar Industria Argentina de Aceros S.A. for the Preliminary Results of the Administrative Review of Silicon Metal from Argentina for the Period November 1, 1997 through October 31, 1998,'' dated November 30, 1999.

Fair Value Comparisons

To determine whether sales of the subject merchandise sold by Acindar and exported to the United States were made at less than normal value (''NV''), we compared export price (''EP'') to the NV, as described in the ''Export Price'' and ''Normal Value'' sections of this notice. Pursuant to section 777A(d)(2) of the Act, we compared the EPs of individual U.S. transactions to monthly weighted-average NVs of the foreign like product. All merchandise sold in the United States was matched to similar merchandise sold in the home market.

Export Price

We based United States price on EP, as defined in section 772(a) of the Act, because Acindar sold the merchandise to an unaffiliated company prior to importation and constructed export price was not otherwise indicated by the facts of record.

We calculated EP based on the packed, delivered, duty-unpaid price to an unaffiliated trading company in the United States. We made deductions pursuant to section 772(c)(2) of the Act for foreign inland freight expenses not reimbursed by the importer, brokerage and handling, and increased the United States price by the amount of foreign inland freight paid by the importer, and duty drawback in accordance with section 772(c)(1)(A) of the Act.

Normal Value (NV)

In order to determine whether sales of the foreign like product in the home market are a viable basis for calculating NV, we compared the volume of home market sales of the foreign like product to the volume of subject merchandise sold in the United States, in accordance with section 773(a)(1)(C) of the Act. Acindar's aggregate volume of home market sales of the foreign like product was greater than five percent of its respective aggregate volume of U.S. sales of the subject merchandise. Therefore, we have based NV on home market sales.

Acindar made sales to affiliated customers in the home market during the period of review and accordingly, we performed the arm's length test. Sales to affiliated companies that failed the test were disregarded, pursuant to section 351.403(c) of the Department's regulations. Home market prices were based on the packed, delivered prices to customers. We made adjustments to NV according to section 773(a)(6)(B) and (C) of the Act, where appropriate, for discounts and rebates, billing adjustments, inland freight net of expenses billed to the customer, credit expenses net of interest revenues, warranty expenses, and packing. Pursuant to section 773(a)(6)(C)(iii) of the Act and section 351.410 of the Department's regulations, we made a circumstances of sale adjustment to NV for U.S. direct selling expenses (credit, warranty and bank charge expenses).

Level of Trade

In accordance with section 773(a)(1)(B) of the Act, to the extent practicable, we determine NV based on sales in the comparison market at the same level of trade (''LOT'') as the EP or CEP transaction. In this case, the record shows that sales in both markets were made at the same LOT. Acindar made sales directly to its customers in the United States and Argentina. There were no differences in the selling functions performed for distributors, end-users or trading companies in either market. Acindar provided only packing, warranties and shipping services to customers in both markets.

Preliminary Results of Review

We preliminarily determine that the following margin exists for the period November 1, 1997 through October 31, 1998:

Company	Margin (percent)
Acindar Industria Argentina de Aceros S.A	2.63

Pursuant to section 351.224 of the Department's regulations, we will disclose the calculations performed to the parties to this proceeding within five days of the date of publication of this notice. An interested party may request a hearing within 30 days of publication. Any hearing, if requested, will be held 44 days after the date of publication, or the first business day thereafter. Issues raised in the hearing will be limited to those raised in the respective case briefs and rebuttal briefs. Interested parties may submit case briefs and rebuttal briefs not later than 30 days and 37 days, respectively, after the date of publication of these preliminary results of review. See 19 CFR 351.309(c)(1)(ii) and (d)(1).

Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument (1) a statement of the issue and (2) a brief summary of the argument. Parties are also encouraged to provide a summary of the arguments not to exceed five pages and a table of statutes, regulations, and cases cited.

The Department will issue the final results of this administrative review, including the results of its analysis of

issues raised in any such written briefs or at the hearing, if held, not later than 120 days after the date of publication of this notice.

Interested parties who wish to request a hearing or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, Room B–099,within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. *See* 19 CFR 351.310(c).

Assessment Rates

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. The Department will issue appropriate appraisement instructions directly to the Customs Service upon completion of this review. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties. We will instruct the Customs Service to assess antidumping duties on all appropriate entries covered by this review if any assessment rate calculated in the final results of this review is above *de minimis* (*i.e,* at or above 0.5 percent) pursuant to section 351.106(c)(2) of the Department's regulations. For assessment purposes, if applicable, we intend to calculate an importer-specific assessment rate by aggregating the dumping margins calculated for all U.S. sales and dividing this amount by the total quantity sold.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon completion of the final results of this administrative review for all shipments of carbon steel wire rod from Argentina entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(1) of the Act: (1) the cash deposit rate for Acindar will be the rate established in the final results of administrative review, except if the rate is less than 0.5 percent, and therefore, *de minimis* within the meaning of 19 CFR 351.106, in which case the cash deposit rate will be zero; (2) for merchandise exported by manufacturers or exporters not covered in this review, but covered in the original less than fair value (LTFV) investigation, the cash deposit rate will continue to be the rate published in the final determination; or (3) if the exporter is not a firm covered in this review or the LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 119.11 percent, the ''All Others'' rate made effective by the LTFV determination. These requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during these review periods. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 10, 1999.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 99–30283 Filed 11–18–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–853]

Initiation of Antidumping Duty Investigation: Circular Seamless Stainless Steel Hollow Products From Japan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: November 19, 1999.

FOR FURTHER INFORMATION CONTACT: Charles Riggle or Constance Handley at (202) 482–0650 and (202) 482–0631, respectively; Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230.

Initiation of Investigation

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (''the Act'') by the Uruguay Round Agreements Act (''URAA''). In addition, unless otherwise indicated, all citations to the Department's regulations are references to the provisions codified at 19 CFR Part 351 (1998).

The Petition

On October 26, 1999, the Department of Commerce (''the Department'') received a petition on circular seamless stainless steel hollow products from Japan filed in proper form by Altx, Inc., American Extruded Products, PMAC Ltd, DMV Stainless USA, Inc., Salem Tube Inc., Sandvik Steel Co. International Extruded Products LLC and the United Steel Workers of America, AFL–CIO/CLC. On November 9, 1999, Pennsylvania Extruded Company (Pexco) joined as a co-petitioner in the case. The Department received supplements to the petition on November 9, 10, and 12, 1999.

In accordance with section 732(b) of the Act, the petitioners allege that imports of circular seamless stainless steel hollow products from Japan are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act, and that such imports are materially injuring an industry in the United States.

The Department finds that the petitioners filed this petition on behalf of the domestic industry because they are interested parties as defined in sections 771(9)(C) and (D) of the Act and they have demonstrated sufficient industry support with respect to the antidumping investigation they are requesting the Department to initiate (*see Determination of Industry Support for the Petition* below).

Scope of Investigation

The scope of this investigation covers seamless stainless hollow products, including pipes, tubes, redraw hollows, and hollow bars, of circular cross section, containing 10.5 percent or more by weight chromium, regardless of production process, outside diameter, wall thickness, length, industry specification (domestic, foreign or proprietary), grade or intended use. Common specifications for the subject seamless stainless steel hollow products include, but are not limited to, ASTM–A–213, ASTM–A–268, ASTM–A–269, ASTM–A–270, ASTM–A–271, ASTM–A–312, ASTM–A–376, ASTM–A–498, ASTM–A–511, ASTM–A–632, ASTM–A–731 ASTM–A–771, ASTM–A–789, ASTM–A–790, ASTM–A–826 and their proprietary or foreign equivalents.

The merchandise covered by this petition is found in the Harmonized

Tariff Schedule of the United States (HTSUS) subheadings 7304.10.50.20, 7304.10.50.50, 7304.10.50.80, 7304.41.30.05, 7304.41.30.15, 7304.41.30.45, 7304.41.60.05, 7304.41.60.15, 7304.41.60.45, 7304.49.00.05, 7304.49.00.15, 7304.49.00.45, 7304.49.00.60. Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive. Excluded from the scope of the investigation are finished oil country tubular goods certified to American Petroleum Institute (''API'') standard 5CT or 5D. Also excluded are hollow drill bars and rods, classifiable under 7228.80 of the HTSUS.

During our review of the petition, we discussed the scope with the petitioners to ensure that the scope in the petition accurately reflects the product for which the domestic industry is seeking relief. Moreover, as discussed in the preamble to the Department's regulations (62 FR 27323), we are setting aside a period for parties to raise issues regarding product coverage. The Department encourages all parties to submit such comments by December 13, 1999. Comments should be addressed to Import Administration's Central Records Unit at Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230. The period of scope consultations is intended to provide the Department with ample opportunity to consider all comments and consult with parties prior to the issuance of the preliminary determination.

Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (1) At least 25 percent of the total production of the domestic like product; and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition.

Section 771(4)(A) of the Act defines the ''industry'' as the producers of a domestic like product. Thus, to determine whether the petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (''ITC''), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to the law.[1]

Section 771(10) of the Act defines the domestic like product as ''a product that is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation,'' *i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition.

After the filing of the petition, we received comments from U.S. redrawers and from Sumitomo Metal Industries, Ltd. (Sumitomo), a Japanese producer of the subject merchandise, requesting that for the purposes of determining industry support, the Department define hot-finished pipe and cold-drawn pipe as separate like products. These parties contend that hot-finished and cold-drawn pipe are made by different companies with different equipment and sold for different uses.

In addition, Sumitomo argues that while the ordinary uses for pipe and tubing can be met by the hot-rolling process, there are uses such as heat exchange, hydraulics, instrumentation, and subsea control and service, which demand greater accuracy, higher physical properties, better surfaces, thinner walls and smaller diameters that require cold-drawing methods. Therefore, both the U.S. redrawers and Sumitomo requested that the Department poll producers of hot-finished and cold-drawn pipe and tube separately to determine if the petitioners have adequate industry support for both types of products.

On November 12, 1999, the petitioners submitted rebuttal comments, stating that with the addition of Pexco, the largest U.S. domestic producer of the subject merchandise, as a petitioner, the petition has clearly been filed on behalf of the U.S. domestic industry whether circular seamless stainless steel hollow products are treated as a single like product, or as two distinct like products.

For purposes of this initiation, we are adopting the domestic like product definition set forth in the petition. Seamless stainless steel hollow products are made along a continuum of sizes and grades, with a degree of substitution of one type of product for another along the continuum. While we recognize that certain differences exist between the products in the proposed like product groupings, we find that the similarities are more significant. For example, all products in the proposed like product groupings share characteristics, such as chemical composition, that make them suitable for uses in pressurized, corrosive, high-temperature environments. Moreover, Sumitomo acknowledged in its November 10, 1999, submission (at 11) that no particular general application is always the exclusive domain of either hot-finished or cold-finished products.

With regard to the assertion that hot-finished and cold-drawn hollow products are manufactured by different companies and with different equipment, given the time constraints placed on the Department, our industry support analysis focuses on the factors specified in section 771(10) of the Act, *i.e.*, physical characteristics and uses of the domestic like product. Moreover, as stated above, based on the evidence available, we find that the similarities outweigh the differences between these products.

Further, several steel cases support our conclusion that hot-finished and cold-drawn products are treated appropriately as a single like product by the Department. *See e.g. Initiation of Antidumping Duty Investigations: Certain Large Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe from Japan and Mexico; and Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe From the Czech Republic, Japan, the Republic of South Africa and Romania*, 64 FR 40825 (July 28, 1999); *Final Determination of Sales at Less Than Fair Value; Stainless Steel Hollow Products from Sweden*, 52 FR 37810 (October 9, 1987); *Small Diameter Circular Seamless Carbon and Alloy Steel Standard, Line and Pressure Pipe From Germany: Final Results of Antidumping Duty Administrative Review*, 63 FR 13217 (March 18, 1998) and *Stainless Steel Bar From Japan: Final Results of Antidumping*

[1] *See Algoma Steel Corp., Ltd.* v. *United States*, 688 F. Supp. 639, 642–44 (CIT 1988); *High Information Content Flat Panel Displays and Display Glass from Japan: Final Determination; Rescission of Investigation and Partial Dismissal of Petition*, 56 FR 32376, 32380–81 (July 16, 1991).

Administrative Review, 64 FR 36333 (July 6, 1999). The facts of this case do not justify departure from our large body of established precedent.

Because the petitioners did not account for more than 50 percent of the domestic production at the time the petition was filed, we polled the industry as directed in 732(c)(4)(D) of the Act. While certain domestic producers [2] expressed opposition to the petition, the entry of Pexco on November 9, 1999, as a petitioner now means that the petitioners account for more than 50 per cent of total production of the domestic like product. As such, they have established the requisite level of industry support. *See Attachment to the Initiation Checklist, Re: Industry Support,* November 15, 1999.

Sumitomo argued further that the Department should have gathered U.S. production data for the period July 1, 1998, through June 30, 1999, rather than calendar year 1998 data, for purposes of its industry support analysis because this period would reflect the most recent state of the industry. With regard to Sumitomo's argument as to the use of 1998 production data, we note that, pursuant to 19 CFR 351.203(e)(1), the Department has discretion in defining the 12-month period for which production will be measured. In this case, we believe that the calender year 1998, which was used in the petition for the purposes of demonstrating industry support, is representative and consistent with Department practice. *See e.g., Initiation Checklist for the Petitions Covering Certain Cold-Rolled Carbon Steel Flat Products from Argentina, Brazil, South Africa, Slovakia, Indonesia, Japan, Thailand, Taiwan, Venezuela, the People's Republic of China, Turkey, and Russia,* dated June 14, 1999, and *Initiation Checklist* for the *Petition Covering Solid Agricultural Grade Ammonium Nitrate from The Russian Federation,* dated June 21, 1999.

Finally, Sumitomo stated that 1998 production by Al Tech, whose seamless pipe production facility was later purchased by the petitioner Altx, should not be considered for purposes of determining industry support. The petitioners claimed that the inclusion of Al Tech's 1998 production is appropriate because the equipment employed in 1998 to produce the like product is now operated by Altx. We note that this is a moot point because, with the entry of Pexco as a petitioner, the inclusion of Al Tech's production is not necessary for the petitioners to demonstrate adequate industry support.

Export Price and Normal Value

The petitioners, in determining normal value (''NV'') for Japan, relied upon price data contained in a confidential market research report filed with the Department. At our request, the petitioners arranged for the Department to contact the authors of the report to verify the accuracy of the data, the methodology used to collect the data, and the credentials of those gathering the market research. The Department's discussion with the authors of the market research reports is summarized in *Memorandum to the File: Re: Foreign Market Research Reports,* dated November 2, 1999.

The petitioners based EP on affidavits of U.S. price offerings for seamless stainless steel hollow products manufactured by Sumitomo, Nippon, and Sanyo during January through April 1999. The petitioners selected seamless stainless hollow products with specifications commonly exported to the United States. In the absence of more definitive information, the petitioners refer to the date of the offer as the date of sale. The affidavits with the sales price offers reflect the prices offered to an unaffiliated customer.

The petitioners calculated a net U.S. price by subtracting estimated costs for shipment from the factory in Japan to the port of export, and Japanese trading company commissions, from the sales price. For a more detailed discussion of the deductions and adjustments relating to home market price, U.S. price, factors of production and sources of data, *see Initiation Checklist,* dated November 15, 1999. Should the need arise to use as facts available under section 776 of the Act any of this information in our preliminary or final determinations, we may re-examine the information and revise the margin calculations, if appropriate.

As further explained below in the ''Initiation of Cost Investigation'' section, the petitioners provided information demonstrating reasonable grounds to believe or suspect that sales of seamless stainless steel hollow products sold in the home market were made at prices below the fully absorbed cost of production (''COP''), within the meaning of section 773(b) of the Act. Pursuant to section 773(b)(3) of the Act, COP consists of the cost of manufacturing (''COM''), selling, general, and administrative expenses (''SG&A'') and packing. To calculate COP, the petitioners based COM on their own production experience, adjusted for known differences between costs incurred to produce seamless stainless steel hollow products in the United States and in Japan using market research and publicly available data.

To calculate SG&A and financial expenses, petitioners relied upon the fiscal year 1998 audited financial statements of a Japanese steel producer. Based upon the comparison of the adjusted prices of the foreign like product in the home market to the calculated COP of the product, we find reasonable grounds to believe or suspect that sales of the foreign like product were made below the COP within the meaning of section 773(b)(2)(A)(i) of the Act. Accordingly, the Department is initiating a country-wide cost investigation.

When we find that sales in the home market are made at prices below cost, we compare EP to constructed value [3] (''CV''). The margin calculations based on price to CV comparisons, indicate dumping margins ranging from 30.86–156.81 percent. The estimated dumping margins, based on price-to-price comparisons, range from 11.72–49.17 percent.

Based on the data provided by the petitioners, there is reason to believe that imports of circular stainless steel hollow products from Japan are being, or are likely to be, sold at less than normal value.

Initiation of Cost Investigation

As noted above, pursuant to section 773(b) of the Act, the petitioners provided specific factual information demonstrating reasonable grounds to believe or suspect that sales in the Japanese home market were made at prices below the fully absorbed COP and, accordingly, requested that the Department conduct a country-wide sales-below-COP investigation in connection with the requested antidumping investigation for Japan. The Statement of Administrative Action accompanying the URAA, H.R. Doc. 103–412 (''SAA''), states that an allegation of sales below COP need not be specific to individual exporters or producers. SAA at 833. The SAA at 833 states that ''Commerce will consider allegations of below-cost sales in the aggregate for a foreign country, just as Commerce currently considers allegations of sales at less than fair value on a country-wide basis for purposes of

[2] These producers are principally redrawers who import, directly or indirectly, at least some of their inputs from Japan.

[3] Pursuant to section 773(e) of the Act, the constructed value is the sum of (1) the cost of materials and fabrication of the subject merchandise, (2) selling, general, and administrative expenses and profit in the foreign market, and (3) the cost of packing for exportation to the United States.

initiating an antidumping investigation.''

Further, the SAA provides that ''new section 773(b)(2)(A) retains the current requirement that Commerce have 'reasonable grounds to believe or suspect' that below cost sales have occurred before initiating such an investigation. 'Reasonable grounds' * * * exist when an interested party provides specific factual information on costs and prices, observed or constructed, indicating that sales in the foreign market in question are at below-cost prices.'' *Id.* Based upon the comparison of the adjusted prices from the petition for the representative foreign like products to their costs of production, we find the existence of ''reasonable grounds to believe or suspect'' that sales of these foreign like products in Japan were made below the COP within the meaning of section 773(b)(2)(A)(i) of the Act. Accordingly, the Department is initiating the requested country-wide cost investigation.

Allegations and Evidence of Material Injury and Causation

The petition alleges that the U.S. industry producing the domestic like products is being materially injured, and is threatened with material injury, by reason of the individual and cumulated imports of the subject merchandise sold at less than NV. The petitioners explained that the industry's injured condition is evident in the declining trends in (1) U.S. market share, (2) average unit sales values, (3) share of domestic consumption, (4) operating income, (5) employment, (6) output, (7) sales, (8) return on investment, (9) capacity utilization, (10) ability to raise capital and (11) cash flow.

The allegations of injury and causation are supported by relevant evidence including U.S. Customs import data, lost sales, and pricing information. The Department assessed the allegations and supporting evidence regarding material injury and causation and determined that these allegations are supported by accurate and adequate evidence and meet the statutory requirements for initiation (*see Attachments to Initiation Checklist, Re: Material Injury,* November 15, 1999).

Initiation of Antidumping Investigation

Based upon our examination of the petition on circular seamless stainless steel hollow products from Japan, we find that the petition meets the requirements of section 732 of the Act. Therefore, we are initiating an antidumping duty investigation to determine whether imports of circular seamless stainless steel hollow products from Japan are being, or are likely to be, sold in the United States at less than fair value. Unless this deadline is extended, we will make our preliminary determinations no later than 140 days after the date of this initiation.

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act, a copy of the public version of the petition has been provided to the representatives of Japan. We will attempt to provide a copy of the public versions of each petition to each exporter named in the petition, as appropriate.

International Trade Commission Notification

We have notified the ITC of our initiations, as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will determine, by no later than December 10, 1999, whether there is a reasonable indication that imports of circular seamless stainless steel hollow products from Japan are causing material injury, or threatening to cause material injury, to a U.S. industry. A negative ITC determination will result in the investigation being terminated; otherwise, this investigation will proceed according to statutory and regulatory time limits.

This notice is published pursuant to section 777(i) of the Act.

Dated: November 15, 1999.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 99–30282 Filed 11–18–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmitted No. 00–17]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSCA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 00–17 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: November 15, 1999.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–10–M

DEFENSE SECURITY COOPERATION AGENCY

WASHINGTON, DC 20301-2800

3 NOV 1999
In reply refer to:
I-99/013509

Honorable J. Dennis Hastert
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 00-17, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance (LOA) to the Netherlands for defense articles and services estimated to cost $225 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Same ltr to: House Committee on International Relations
Senate Committee on Appropriations
Senate Committee on Foreign Relations
House Committee on National Security
Senate Committee on Armed Services
House Committee on Appropriations

Transmittal No. 00-17

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act (U)

(i) **Prospective Purchaser: The Netherlands**

(ii) **Total Estimated Value:**

Major Defense Equipment*	$ 179 million
Other	$ 46 million
TOTAL	$ 225 million

(iii) **Description of Articles or Services Offered: Thirty APACHE AN/APG-78 Longbow Fire Control Radar with APR-48A Radar Frequency Interferometer, test and support equipment, spare and repair parts, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical support and other related elements of logistics support.**

(iv) **Military Department: Army (WAH)**

(v) **Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None**

(vi) **Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached**

(vii) **Date Report Delivered to Congress: 3 NOV 1999**

POLICY JUSTIFICATION

The Netherlands - APACHE Longbow Fire Control Radar with Radar Frequency Interferometer

The Government of the Netherlands has requested a possible sale for remanufacture of 30 APACHE AN/APG-78 Longbow Fire Control Radar with APR-48A Radar Frequency Interferometer, test and support equipment, spare and repair parts, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor technical support and other related elements of logistics support. The estimated cost is $225 million.

This proposed sale will contribute to the foreign policy and national security of the United States by improving the military capabilities of Netherlands and enhancing weapon system standardization and interoperability of this important NATO ally.

The Netherlands desires these articles to fulfill their strategic commitments for self-defense, with coalition support, in the region. The proposed sale will upgrade its anti-armor day/night missile capability, provide for the defense of vital installations and provide close air support for the military ground forces. The Netherlands will have no difficulty absorbing these radar into its armed forces.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The principal contractors will be Lockheed Martin Federal Systems, Owego, New York; and Longbow LLC, Orlando, Florida. One or more proposed offset agreements may be related to this proposed sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government and contractor representatives to the Netherlands.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 00-17

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

Annex
Item No. vi

(vi) Sensitivity of Technology:

1. The AH-64D APACHE Attack Helicopter includes the following classified or sensitive components:

a. AN/APG-78 AH-64D Longbow Fire Control Radar (FCR) is an active fire control radar system providing detection, location, classification and prioritization of targets to be prosecuted by the Longbow HELLFIRE Modular Missile System or handed over to other on-board sensor systems. This enables the APACHE helicopter to detect and fire upon targets in visual conditions which preclude the use of visual or infrared imaging systems. Hardware is Unclassified; releasable technical manuals for operation and organic level maintenance are Unclassified. The data, including operational software, proposed for release will not, in itself, facilitate reverse engineering.

b. The AN/APR-48A Radar Frequency Interferometer (RFI) is part of the AN/APG-78 FCR. It passively detects, locates in azimuth, and identifies radar emitters and sends the emitter identification and location to either the FCR or to the APACHE Weapons Processor for display to the aircrew. Emitter information can also be used to prioritization. Hardware is classified Confidential when the User Data Module (UDM) is attached to the RFI Processor Assembly, Unclassified when the UDM is absent. Releasable technical manuals for operation and organic level maintenance are Unclassified. The data, including operational software, proposed for release will not facilitate reverse engineering.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that the Netherlands can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

[FR Doc. 99–30207 Filed 11–18–99; 8:45 am]
BILLING CODE 5001–10–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 00–18]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSCA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 00–18 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: November 15, 1999.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–10–M

DEFENSE SECURITY COOPERATION AGENCY

WASHINGTON, DC 20301-2800

3 NOV 1999
In reply refer to:
I-99/013561

Honorable J. Dennis Hastert
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 00-18, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance (LOA) to United Kingdom for defense articles and services estimated to cost $50 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Same ltr to: House Committee on International Relations
Senate Committee on Appropriations
Senate Committee on Foreign Relations
House Committee on National Security
Senate Committee on Armed Services
House Committee on Appropriations

Transmittal No. 00-18

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) Prospective Purchaser: United Kingdom

(ii) Total Estimated Value:

Major Defense Equipment*	$ 45 million
Other	$ 5 million
TOTAL	$ 50 million

(iii) Description of Articles or Services Offered: Twenty conventionally armed TOMAHAWK BLOCK IIIC Land Attack Missiles (TLAM), containers, engineering technical assistance, spare and repair parts, and other related elements of logistics support

(iv) Military Department: Navy (AHB)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached

(vii) Date Report Delivered to Congress: 03 NOV 1999

POLICY JUSTIFICATION

United Kingdom - TOMAHAWK BLOCK IIIC Land Attack Missiles

The Government of United Kingdom has requested a possible sale of 20 conventionally armed TOMAHAWK BLOCK IIIC Land Attack Missiles (TLAM), containers, engineering technical assistance, spare and repair parts, and other related elements of logistics support. The estimated cost is $50 million.

This proposed sale will contribute to the foreign policy and national security of the United States by improving the military capabilities of United Kingdom and enhancing weapon system standardization and interoperability of this important NATO ally.

The United Kingdom needs these missiles to augment their present operational inventory and to enhance their submarine launched capability. The missiles will enhance United Kingdom operational effectiveness in support of NATO. The United Kingdom, which already has TOMAHAWK missiles in its inventory, will have no difficulty absorbing these additional missiles.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The prime contractor will be Raytheon Missile Systems Company, Tucson, Arizona. There are no offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government and contractor representatives to United Kingdom.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 00-18

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex
Item No. vi

(vi) Sensitivity of Technology:

1. The conventionally armed TOMAHAWK BLOCK IIIC Land Attack Missile (TLAM) consists of the following classified components:

a. The TOMAHAWK missile (Complete) - Guidance Set, Digital Scene Matching Area Correlator (DSMAC) Global Positioning System (GPS) when software is installed, Data Link when software/firmware is installed, Common Missile Radar Altimeter (CMRA), Operational Flight Software as well as DSMAC and GPS flight software.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapon system effectiveness. The consequences of loss of this technology to a technologically advanced or competent adversary could result in the development of countermeasures or equivalent systems which could reduce weapons system effectiveness or be used in the development of a system which similar advanced capabilities.

3. A determination has been made that United Kingdom can provide substantially the same degree of protection for this technology as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

[FR Doc. 99–30208 Filed 11–18–99; 8:45 am]
BILLING CODE 5001–10–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 00–20]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSCA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 00–20 with attached transmittal and policy justification.

Dated: November 15, 1999.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–10–M

DEFENSE SECURITY COOPERATION AGENCY

WASHINGTON, DC 20301-2800

3 NOV 1999
In reply refer to:
I-99/013787

Honorable J. Dennis Hastert
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 00-20 and under separate cover the classified annex thereto. This Transmittal concerns the Department of the Army's proposed Letter(s) of Offer and Acceptance (LOA) to the Netherlands for defense articles and services estimated to cost $515 million. Soon after this letter is delivered to your office, we plan to notify the news media of the unclassified portion of this Transmittal.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Separate Cover:
Classified Annex

Same ltr to: House Committee on International Relations
Senate Committee on Appropriations
Senate Committee on Foreign Relations
House Committee on National Security
Senate Committee on Armed Services
House Committee on Appropriations

Transmittal No. 00-20

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) Prospective Purchaser: The Netherlands

(ii) Total Estimated Value:

Major Defense Equipment*	$ 470 million
Other	$ 45 million
TOTAL	$ 515 million

(iii) Description of Articles or Services Offered: One hundred twenty-eight PATRIOT Advance Capability-3 (PAC-3) guided missiles, trainers, support equipment, spare and repair parts, modification kits, fire solution computer, publications, U.S. Government and contractor engineering and logistics support services, personnel training and equipment and other related elements of logistic support.

(iv) Military Department: Army (WZM, WZO and WZQ)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: none

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached

(vii) Date Report Delivered to Congress: 3 NOV 1999

POLICY JUSTIFICATION

The Netherlands - PAC-3 PATRIOT Missiles

The Government of the Netherlands has requested a possible sale of 128 PATRIOT Advance Capability-3 (PAC-3) guided missiles, trainers, support equipment, spare and repair parts, modification kits, fire solution computer, publications, U.S. Government and contractor engineering and logistics support services, personnel training and equipment and other related elements of logistic support. The estimated cost is $515 million.

This proposed sale will contribute to the foreign policy and national security of the United States by improving the military capabilities of Netherlands and enhancing weapon system standardization and interoperability of this important NATO ally.

This proposed sale will provide the Netherlands with an effective, state-of-the-art anti-tactical missile capability and will greatly improve the defense posture of the Netherlands as well as other NATO countries. The Netherlands will have no difficulty absorbing these PAC-3 missiles into their inventory.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The principal contractors will be Lockheed Martin Federal Systems, Owego, New York; and Longbow LLC, Orlando, Florida. One or more proposed offset agreements may be related to this proposed sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government and contractor representatives to the Netherlands.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 99–30209 Filed 11–18–99; 8:45 am]
BILLING CODE 5001–10–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 00–21]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of P.L. 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSCA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 00–21 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: November 15, 1999.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–10–M

DEFENSE SECURITY COOPERATION AGENCY

WASHINGTON, DC 20301-2800

3 NOV 1999
In reply refer to:
I-99/001028

Honorable J. Dennis Hastert
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 00-21, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance (LOA) to the Republic of Korea for defense articles and services estimated to cost $4.2 billion. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Same ltr to: **House Committee on International Relations**
Senate Committee on Appropriations
Senate Committee on Foreign Relations
House Committee on National Security
Senate Committee on Armed Services
House Committee on Appropriations

Transmittal No. 00-21

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) Prospective Purchaser: Republic of Korea

(ii) Total Estimated Value:

Major Defense Equipment*	$ 3.1 billion
Other	$ 1.1 billion
TOTAL	$ 4.2 billion

(iii) Description of Articles or Services Offered: Fourteen PATRIOT Advance Capability 3 (PAC 3) fire units consisting of: 14 AN/MPQ-53 radar sets, 14 AN/MSQ-104 engagement control stations, 76 M091 launching stations, 31 OA-9054(V)41G antenna mast groups, 14 electric power plants with dual 150kw generators; 616 MIM-104D missiles; 333 SINCGARS, Cooperative Logistics Supply Support Arrangement, PATRIOT Field Army Support Center and trainers, trucks, trailers, fuzes, communication relay groups, power units, information coordination centrals, battalion maintenance group and equipment, tool kits, publications and technical documentations, calibration equipment, transporters, precision lightweight global positioning system receiver, kits, generators, shop and tool equipment, spare and repair parts, support and test equipment, personnel training and training equipment, U.S. Government and contractor engineering and logistics support services, Quality Assurance Team and Mobile Training Teams, technical assistance and support, and other related elements of logistics support.

(iv) Military Department: Army (YTC, YTD, BPJ, BPK, OFQ, KVZ, and KWP)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: none

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached.

(vii) Date Report Delivered to Congress: 3 NOV 1999

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Republic of Korea - PATRIOT Advance Capability-3 Fire Unit and Missiles

The Republic of Korea has requested a possible sale of 14 PATRIOT Advance Capability 3 (PAC 3) fire units consisting of: 14 AN/MPQ-53 radar sets, 14 AN/MSQ-104 engagement control stations, 76 M091 launching stations, 31 OA-9054(V)41G antenna mast groups, 14 electric power plants with dual 150kw generators; 616 MIM-104D missiles; 333 SINCGARS, Cooperative Logistics Supply Support Arrangement, PATRIOT Field Army Support Center and trainers, trucks, trailers, fuzes, communication relay groups, power units, information coordination centrals, battalion maintenance group and equipment, tool kits, publications and technical documentations, calibration equipment, transporters, precision lightweight global positioning system receiver, kits, generators, shop and tool equipment, spare and repair parts, support and test equipment, personnel training and training equipment, U.S. Government and contractor engineering and logistics support services, Quality Assurance Team and Mobile Training Teams, technical assistance and support, and other related elements of logistics support. The estimated cost is $4.2 billion.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country which has been and continues to be an important force for political stability and economic progress in Northeast Asian.

This proposed sale will enhance their defensive capability against hostile neighbors lessening the burden on the United States. Korea will have no difficulty absorbing the PAC 3 and missiles into its armed forces.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The prime contractor will be Raytheon Corporation, Andover, Massachusetts. One or more proposed offset agreements may be related to this proposed sale.

Implementation of this proposed sale will require the assignment of 26 contractor representatives up to two years. There may be a Quality Assurance Team in-country periodically as the program proceeds.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 00-21

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

Annex
Item No. vi

(vi) Sensitivity of Technology:

1. The AN/MPQ-53 semi-trailer mounted radar set and MIM-104D missiles including seeker and fuze are classified Confidential elements of the PATRIOT Missile System. Parts of the Technical Data Package are classified Confidential or Secret. The highest level of classified information required to be released for training, operation, and maintenance of the PATRIOT missiles system is Secret. The highest level which could be revealed through reverse engineering or testing of the end item is Secret. This information includes Confidential and Secret reports and test data, as well as performance and capability data classified Confidential/Secret.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that Korea can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

[FR Doc. 99–30210 Filed 11–18–99; 8:45 am]
BILLING CODE 5001–10–C

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Threat Reduction agency (DTRA); Membership of the Defense Threat Reduction Agency Performance Review Board

AGENCY: Department of Defense, Defense Threat Reduction Agency.

ACTION: Notice of membership of the Defense Threat Reduction Agency Performance Review Board.

SUMMARY: This notice announces the appointment of the members of the Performance Review Board (PRB) of the Defense Threat Reduction Agency. The publication of PRB membership is required by 5 U.S.C. 4314(c)(4). The Performance Review Board shall provide fair and impartial review of Senior Executive Service performance appraisals and make recommendations regarding performance and performance awards to the Director, Defense Threat Reduction Agency.

EFFECTIVE DATE: The effective date of service for the appointees of the DTRA PRB is on or about 19 November 1999.

FOR FURTHER INFORMATION CONTACT: D. DIAL–ALFRED, Civilian Personnel Management Division (MPC), (703) 325–1106, Defense Threat Reduction Agency, Alexandria, Virginia, 22310–3398.

SUPPLEMENTARY INFORMATION: The names and titles of the members of the DTRA PRB are set forth below. All are DTRA officials unless otherwise identified:

Mr. Robert L. Brittigan, Office of General Counsel
Mr. Michael K. Evenson, Deputy Director, Nuclear Support Directorate
Mr. Timothy X. Morgan, Director, Programs, Resources and Assessments, Special Operations and Low-Intensity Conflict, Combating Terrorism, Office of the Assistant Secretary Office of Defense.

The following DTRA officials will serve as alternate members of the DTRA PRB, as appropriate.

Mr. Joe Golden, Staff Specialist for Special Technology Programs
Mr. Richard L. Gullickson, Chief, Simulation and Test Division
Mr. Myron K. Kunka, Comptroller
Dr. Don A. Linger, Deputy for Technical Programs
Mr. Clifton B. McFarland, Jr., Director for Weapons Effects
Mr. Vayl S. Oxford, Deputy Director for Counterproliferation Support and Operations Directorate
Mrs. Joan Ma Pierre, Chief, Systems Survivability Division
Dr. Michael J. Shore, Chief, Force Protection and Technology Applications Division
Mr. Peter Sullivan, Deputy Director, Technology Security
Dr. Leon A. Wittwer, Chief, Collateral Effects Branch

Dated: November 15, 1999.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 99–30206 Filed 11–18–99; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the Chief of Naval Operations (CNO) Executive Panel

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: The CNO Executive Panel is to conduct the final briefing of the Short Study on Navy and Alliance Structures Part I to the Chief of Naval Operations. This meeting will consist of discussions relating to Navy interoperability with allied and coalition partners.

DATES: The meeting will be held on December 1, 1999 from 10:00 a.m. to 11:00 a.m.

ADDRESSES: The meeting will be held at the Office of the Chief of Naval Operations, 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Commander Christopher Agan, CNO Executive Panel, 4401 Ford Avenue, Suite 601, Alexandria, Virginia 22302–0268, Telephone number (703) 681–6205.

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2), these matters constitute classified information that is specifically authorized by Executive Order to be kept secret in the interest of national defense and are, in fact, properly classified pursuant to such Executive Order. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 5 U.S.C., section 5529(b)(2).

Dated: November 8, 1999.

J.L. Roth,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 99–30190 Filed 11–18–99; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the Chief of Naval Operations (CNO) Executive Panel

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: The CNO Executive Panel is to conduct the final briefing of the Congressional Support Short Study to the Chief of Naval Operations. This meeting will consist of discussions relating to Navy liaison with Capitol Hill.

DATES: The meeting will be held on December 15, 1999, from 10:00 a.m. to 11:00 a.m.

ADDRESSES: The meeting will be held at the office of the Chief of Naval Operations, 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONCERNING THIS MEETING CONTACT: Commander Christopher Agan, CNO Executive Panel, 4401 Ford Avenue, Suite 601, Alexandria, Virginia 22302–0268, (703) 681–6205.

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2), these matters constitute information that relates solely to the internal rules and practices of the agency. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in 5 U.S.C., section 552b(c)(2).

Dated: November 9, 1999.

J.L. Roth,

Lieutenant Commander, Judge Advocate General's Corps, Federal Register Liaison Officer.

[FR Doc. 99–30191 Filed 11–18–99; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Leader, Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before December 20, 1999.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Danny Werfel, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW, Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the internet address DWERFEL@OMB.EOP.GOV.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: November 15, 1999.

William E. Burrow,

Leader, Information Management Group, Office of the Chief Information Officer.

Office of Special Education and Rehabilitative Services

Type of Review: New.

Title: Annual Protection and Advocacy of Individual Rights (PAIR) Program Performance Report.

Frequency: Annually.

Affected Public: Not-for-profit institutions; State, local or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 57

Burden Hours: 342

Abstract: Form RSA–509 will be used to analyze and evaluate the Protection and Advocacy of Individual Rights (PAIR) Program administered by eligible systems in states. These systems provide services to eligible individuals with disabilities to protect their legal and human rights.

Requests for copies of the proposed information collection request should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 5624, Regional Office Building 3, Washington, DC 20202–4651, or should be electronically mailed to the internet address *OCIO__IMG__Issues@ed.gov* or should be faxed to 202–708–9346.

For questions regarding burden and/or the collection activity requirements, contact Sheila Carey at 202–708–6287 or electronically mail her at internet address sheila__carey@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 99–30196 Filed 11–18–99; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

State Energy Program Special Projects Financial Assistance

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice for 2000 State Energy Program Special Projects.

SUMMARY: As options offered under the State Energy Program (SEP) for fiscal year 2000, the Office of Energy Efficiency and Renewable Energy is announcing the availability of financial assistance to States for a group of special project activities. Funding is being provided by a number of end-use sector programs in the Office of Energy Efficiency and Renewable Energy. States may apply to undertake any of the projects being offered by these programs. States will be awarded separate grants for special projects, to be carried out in conjunction with their efforts under SEP. The special projects funding and activities are tracked separately so that the end-use sector programs may follow the progress of their projects.

The projects must meet the relevant requirements of the program providing the funding, as well as of SEP, as specified in the program guidance/solicitation. Among the goals of the special projects activities are to assist States to: accelerate deployment of energy efficiency and renewable energy technologies; facilitate the acceptance of emerging and underutilized energy efficiency and renewable energy technologies; and increase the responsiveness of Federally funded technology development efforts to private sector needs.

DATES: The program guidance/solicitation will be available on November 22, 1999. Applications must be received by February 22, 2000.

ADDRESSES: Complete information about this program, including phone numbers for the State SEP offices and a question and answer forum, is available at the following website: http://www.eren.doe.gov/buildings/state__energy/fy00/sepsp00-forum. Otherwise, for referral to the appropriate DOE Regional Office or State Office, you may contact Mr. Thomas Stapp, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586–2096.

SUPPLEMENTARY INFORMATION: Fiscal year 2000 is the fifth year special project activities have been funded in conjunction with the State Energy Program (10 CFR part 420). Most of these State-oriented special projects are related to or based on similar efforts that have been funded separately by the various DOE end-use sector programs that are now providing funding for these optional SEP activities.

Availability of Fiscal Year 2000 Funds

With this publication, DOE is announcing the availability of an estimated $14 million in financial assistance funds for fiscal year 2000. The estimated funds available are based on fiscal year 2000 budget requests and are subject to adjustment after program appropriations are known. The awards will be made though a competitive process. The end-use sector programs that are participating in the SEP special projects for fiscal year 2000, with the estimated amount of funding available for each, are as follows:

- Clean Cities/Alternative Fuels: Accelerating the introduction and increasing the use of alternative fuels and alternative fueled vehicles through the development of infrastructure and clean corridors, and promoting the use of advanced transportation technologies ($2,700,000).
- Industrial Technologies: Implementing Industries of the Future at the State level by building partnerships among State industries: to develop new technologies tied to Industries of the Future road maps and visions; and to utilize best practices which can improve energy efficiency, environmental

performance and productivity ($2,800,000).

- Codes and Standards: Supporting States' actions to update, implement, and enforce residential and commercial building energy codes ($4,200,000).
- Rebuild America: Helping community and regional partnerships improve commercial and multifamily building energy efficiency ($1,600,000).
- Building America: Applying systems engineering approaches to the development of advanced residential buildings, including production techniques, products and technologies that result in higher quality, energy efficient housing ($300,000).
- Federal Energy Management Program: Developing Federal/State partnerships to increase technical capability and funding for energy efficiency, renewable energy, and water conservation measures for Federal buildings ($950,000).
- Hydrogen Reformer Field Verification: Siting and operating small advanced hydrogen reformer systems to better understand and document the performance, maintenance, operation and economic viability of these systems ($500,000).
- Wind Energy Case Studies: Performing case studies documenting the benefits and costs of deployment of 25 to 50 megawatt state of the art wind projects ($500,000).
- Biomass Power Projects: Identifying low-cost project opportunities for the introduction and utilization of biomass power technologies for recovering energy from animal wastes while preventing pollution ($250,000).
- Photovoltaic Projects: Demonstrating photovoltaic technologies ($250,000).

Restricted Eligibility

Eligible applicants for purposes of funding under this program are limited to the 50 States, the District of Columbia, Puerto Rico, and any territory or possession of the United States, specifically, the State energy or other agency responsible for administering the State Energy Program pursuant to 10 CFR part 420. For convenience, the term State in this notice refers to all eligible State applicants.

The Catalog of Federal Domestic Assistance number assigned to the State Energy Program Special Projects is 81.119.

Requirements for cost sharing contributions will be addressed in the program guidance/solicitation for each special project activity, as appropriate. Cost sharing contributions beyond any required percentage are desirable.

Any application must be signed by an authorized State official, in accordance with the program guidance/solicitation.

Evaluation Review and Criteria

A first tier review for completeness will occur at the appropriate DOE Regional Office. Applications found to be complete will undergo a merit review process by panels comprised of members representing the participating end-use sector programs in DOE's Office of Energy Efficiency and Renewable Energy. The end-use sector offices select projects for funding. The Office of Building Technology Assistance then recommends project allocations to the Assistant Secretary for Energy Efficiency and Renewable Energy for final determination. DOE reserves the right to fund, in whole or in part, any, all or none of the applications submitted in response to this notice.

Issued in Washington, DC, on November 15, 1999.

Dan W. Reicher,

Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 99–30216 Filed 11–18–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER99–4355–000, ER99–4356–000, ER99–4357–000, ER99–4358–000, ER99–4359–000, ER99–4363–000, ER99–4503–000 and ER00–22–000]

Middletown Power LLC, Montville Power LLC, Norwalk Power LLC, Devon Power LLC, Connecticut Jet Power LLC, Northeast Generation Company, PP&L Great Works, LLC and Reliant Energy Osceola, LLC (Not Consolidated); Notice of Issuance of Order

November 15, 1999.

Middletown Power LLC, Montville Power LLC, Norwalk Power LLC, Devon Power LLC, Connecticut Jet Power LLC, Northeast Generation Company, PP&L Great Works, LLC, and Reliant Energy Osceola, LLC (hereafter, ''the Applicants'') filed with the Commission rate schedules in the above-captioned proceedings, respectively, under which the Applicants will engage in wholesale electric power and energy transactions at market-based rates, and for certain waivers and authorizations. In particular, certain of the Applicants may also have requested in their respective applications that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liabilities by the Applicants. On November 10, 1999, the Commission issued an order that accepted the rate schedules for sales of capacity and energy at market-based rates (Order), in the above-docketed proceedings.

The Commission's November 10, 1999 Order granted, for those Applicants that sought such approval, their request for blanket approval under Part 34, subject to the conditions found in Appendix B in Ordering Paragraphs (2), (3), and (5):

(2) Within 30 days of the date of this order, any person desiring to be heard or to protest the Commission's blanket approval of issuances of securities or assumptions of liabilities by the Applicants should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211 and 385.214.

(3) Absent a request to be heard within the period set forth in Ordering Paragraph (2) above, if the Applicants have requested such authorization, the Applicants are hereby authorized to issue securities and assume obligations and liabilities as guarantor, indorser, surety or otherwise in respect of any security of another person; provided that such issue or assumption is for some lawful object within the corporate purposes of the Applicants, compatible with the public interest, and reasonably necessary or appropriate for such purposes.

(5) The Commission reserves the right to modify this order to require a further showing that neither public nor private interests will be adversely affected by continued Commission approval of the Applicants' issuances of securities or assumptions of liabilities. * * *

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is December 10, 1999.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE, Washington, DC 20426. This issuance may also be viewed on the Internet at *http://www.ferc.fed.us/*online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 99–30193 Filed 11–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting

The following notice of meeting is published pursuant to section 3(A) of the Goverment in the Sunshine Act (Pub. L. No. 94–409), 5 U.S.C 552B:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: November 23, 1999, 10:00 a.m.

PLACE: Room 2C, 888 First Street, NE, Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

***Note:** Items Listed on the Agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: David P. Boergers, Secretary, Telephone (202) 208–0400. For a recording listing items stricken from or added to the meeting, call (202) 208–1627.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the Agenda; however, all public documents may be examined in the Reference and Information Center.

Consent Agenda—Hydro, 730TH—Meeting November 23, 1999, Regular Meeting (10:00 a.m.)

CAH–1.
DOCKET# P–5984, 004, NIAGARA MOHAWK POWER CORPORATION AND ERIE BOULEVARD HYDROPOWER, L.P.
CAH–2.
DOCKET# P–4797, 050, COGENERATION, INC.
CAH–3.
DOCKET# EL95–49, 000, FOURTH BRANCH ASSOCIATES AND NIAGARA MOHAWK POWER CORPORATION
OTHER#S P–6032, 028, NIAGARA MOHAWK POWER CORPORATION AND FOURTH BRANCH ASSOCIATES

Consent Agenda—Electric

CAE–1.
DOCKET# ER99–4530, 000, ILLINOIS POWER COMPANY
OTHER#S ER99–4415, 000, ILLINOIS POWER COMPANY
CAE–2.
DOCKET# ER99–4527, 000, ISO NEW ENGLAND, INC.
OTHER#S ER99–4536, 000, NEW ENGLAND POWER POOL
ER99–4591, 000, NEW ENGLAND POWER POOL
CAE–3.
DOCKET# ER99–4560, 000, IDAHO POWER COMPANY
CAE–4.
DOCKET# ER99–3427, 000, SOWEGA POWER LLC
CAE–5.
DOCKET# ER99–4545, 000, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
CAE–6.
DOCKET# ER99–4577, 000, ARIZONA PUBLIC SERVICE COMPANY
CAE–7.
DOCKET# ER99–4470, 000, COMMONWEALTH EDISON COMPANY
CAE–8.
OMITTED
CAE–9.
DOCKET# ER00–33, 000, AES PLACERITA, INC.
OTHER#S ER00–38, 000, BROAD RIVER ENERGY LLC
ER00–56, 000, FPL ENERGY WISCONSIN WIND, LLC
ER00–107, 000, LA PALOMA GENERATING COMPANY, LLC
ER00–136, 000, FORTISUS ENERGY CORPORATION
CAE–10.
DOCKET# ER00–26, 000, CENTRAL MAINE POWER COMPANY
CAE–11.
DOCKET# ER00–67, 000, NEW YORK INDEPENDENT SYSTEM OPERATOR, INC., CENTRAL HUDSON GAS & ELECTRIC CORPORATION, CONSOLIDATED EDISON COMPANY OF NEW YORK, INC., LONG ISLAND LIGHTING COMPANY, NEW YORK STATE ELECTRIC & GAS CORPORATION, NIAGARA MOHAWK POWER CORPORATION, ORANGE & ROCKLAND UTILITIES, INC., ROCHESTER GAS AND ELECTRIC CORPORATION AND NEW YORK POWER POOL
CAE–12.
DOCKET# ER00–80, 000, ATLANTIC CITY ELECTRIC COMPANY
OTHER#S ER00–81, 000, DELMARVA POWER & LIGHT COMPANY
CAE–13.
DOCKET# ER99–3621, 000, ISO NEW ENGLAND INC.
OTHER#S ER00–69, 000, NEW ENGLAND POWER COMPANY AND ISO NEW ENGLAND INC.
CAE–14.
OMITTED
CAE–15.
DOCKET# EC99–18, 000, BOSTON EDISON COMPANY
OTHER#S EC99–18, 001, BOSTON EDISON COMPANY
EL99–22, 000, BOSTON EDISON COMPANY
EL99–22, 001, BOSTON EDISON COMPANY
ER99–1023, 000, BOSTON EDISON COMPANY
ER99–1023, 001, BOSTON EDISON COMPANY
ER93–150, 014, BOSTON EDISON COMPANY
EL93–10, 008, BOSTON EDISON COMPANY
EL93–150, 015, BOSTON EDISON COMPANY
EL93–10, 009, BOSTON EDISON COMPANY
ER86–645, 008, BOSTON EDISON COMPANY
ER86–645, 009, BOSTON EDISON COMPANY
CAE–16.
DOCKET# ER99–3719, 000, MOUNTAIN WEST INDEPENDENT SYSTEM ADMINISTRATION
OTHER#S EC99–100, 000, SIERRA PACIFIC POWER COMPANY AND NEVADA POWER COMPANY
CAE–17.
DOCKET# ER97–1523, 010, NEW YORK INDEPENDENT SYSTEM OPERATOR, INC., CENTRAL HUDSON GAS & ELECTRIC CORPORATION, CONSOLIDATED EDISON COMPANY OF NEW YORK, INC., LONG ISLAND LIGHTING COMPANY, NEW YORK STATE ELECTRIC AND GAS CORPORATION, NIAGARA MOHAWK POWER CORPORATION, ORANGE AND ROCKLAND UTILITIES, INC., ROCHESTER GAS AND ELECTRIC CORPORATION AND NEW YORK POWER POOL
OTHER#S OA97–470, 009, NEW YORK INDEPENDENT SYSTEM OPERATOR, INC., CENTRAL HUDSON GAS & ELECTRIC CORPORATION, CONSOLIDATED EDISON COMPANY OF NEW YORK, INC., LONG ISLAND LIGHTING COMPANY, NEW YORK STATE ELECTRIC AND GAS CORPORATION, NIAGARA MOHAWK POWER CORPORATION, ORANGE AND ROCKLAND UTILITIES, INC., ROCHESTER GAS AND ELECTRIC CORPORATION AND NEW YORK POWER POOL
ER97–4234, 007, NEW YORK INDEPENDENT SYSTEM OPERATOR, INC., CENTRAL HUDSON GAS & ELECTRIC CORPORATION, CONSOLIDATED EDISON COMPANY OF NEW YORK, INC., LONG ISLAND LIGHTING COMPANY, NEW YORK STATE ELECTRIC AND GAS CORPORATION, NIAGARA MOHAWK POWER CORPORATION, ORANGE AND ROCKLAND UTILITES, INC., ROCHESTER GAS AND ELECTRIC CORPORATION AND NEW YORK POWER POOL
CAE–18.
DOCKET# OA96–200, 008, EL PASO ELECTRIC COMPANY
OTHER#S EL98–44, 000, SOUTHWESTERN PUBLIC SERVICE COMPANY V. EL PASO ELECTRIC COMPANY
CAE–19.
DOCKET# ER85–477, 018, SOUTHWESTERN PUBLIC SERVICE COMPANY
CAE–20.
DOCKET# ER97–1523, 009, CENTRAL HUDSON GAS & ELECTRIC CORPORATION, CONSOLIDATED EDISON COMPANY OF NEW YORK, INC., LONG ISLAND LIGHTING COMPANY, NEW YORK POWER AUTHORITY, NEW YORK STATE ELECTRIC & GAS CORPORATION, NIAGARA MOHAWK POWER CORPORATION, ORANGE AND ROCKLAND UTILITIES, INC. AND ROCHESTER GAS AND ELECTRIC CORPORATION

OTHER#S OA97–470, 008, CENTRAL HUDSON GAS & ELECTRIC CORPORATION, CONSOLIDATED EDISON COMPANY OF NEW YORK, INC.,LONG ISLAND LIGHTING COMPANY, NEW YORK POWER AUTHORITY, NEW YORK STATE ELECTRIC & GAS CORPORATION, NIAGARA MOHAWK POWER CORPORATION, ORANGE AND ROCKLAND UTILITIES, INC. AND ROCHESTER GAS AND ELECTRIC CORPORATION
ER97–4234, 006, CENTRAL HUDSON GAS & ELECTRIC CORPORATION, CONSOLIDATED EDISON COMPANY OF NEW YORK, INC., LONG ISLAND LIGHTING COMPANY, NEW YORK POWER AUTHORITY, NEW YORK STATE ELECTRIC & GAS CORPORATION, NIAGARA MOHAWK POWER CORPORATION, ORANGE AND ROCKLAND UTILITIES, INC. AND ROCHESTER GAS AND ELECTRIC CORPORATION
CAE–21. OMITTED
CAE–22.
DOCKET# ER99–2776, 001, AMEREN OPERATING COMPANIES
CAE–23.
DOCKET# ER99–4226, 001, AMEREN OPERATING COMPANIES
OTHER#S EL00–16, 000, AMEREN OPERATING COMPANIES
CAE–24.
DOCKET# EL99–94, 000, FORT JAMES OPEARTING COMPANY AND PP&L GREAT WORKS, LLC
CAE–25.
DOCKET# EL99–80, 000, U.S. STEEL GROUP AND SOUTH WORKS POWER COMPANY
CAE–26.
DOCKET# EL99–82, 000, AMERICAN ELECTRIC POWER SERVICE CORPORATION
CAE–27.
DOCKET# EL99–85, 000, SIERRA PACIFIC POWER COMPANY
CAE–28.
DOCKET# EL98–31, 000, WEST TEXAS UTILITIES COMPANY
OTHER#S EL98–33, 000, WEST TEXAS UTILITIES COMPANY, CENTRAL POWER AND LIGHT COMPANY AND PUBLIC SERVICE COMPANY OF OKLAHOMA
CAE–29.
DOCKET# EL99–83, 000, ILLINOIS POWER COMPANY AND AMERGEN ENERGY COMPANY, L.L.C.
OTHER#S ER99–754, 001, ILLINOIS POWER COMPANY AND AMERGEN ENERGY COMPANY, L.L.C.
CAE–30. OMITTED
CAE–31.
DOCKET# EL00–3, 000, ILLINOIS MUNICIPAL ELECTRIC AGENCY V. COMMONWEALTH EDISON COMPANY AND COMMONWEALTH EDISON COMPANY OF INDIANA
OTHER#S EL00–4, 000, ILLINOIS MUNICIPAL ELECTRIC AGENCY V. ILLINOIS POWER COMPANY
CAE–32.
DOCKET# EL00–2, 000, NORTHEAST TEXAS ELECTRIC COOPERATIVE, INC. AND UPSHUR-RURAL ELECTRIC COOPERATIVE CORPORATION V. CSW OPERATING COMPANIES,

CONSENT AGENDA—GAS AND OIL

CAG–1.
DOCKET# RP97–13, 002, EAST TENNESSEE NATURAL GAS COMPANY
CAG–2.
DOCKET# RP00–32, 000, NAUTILUS PIPELINE COMPANY, L.L.C.
CAG–3.
DOCKET# RP00–35, 000, VIKING GAS TRANSMISSION COMPANY
CAG–4.
DOCKET# RP96–272, 012, NORTHERN NATURAL GAS COMPANY
CAG–5. OMITTED
CAG–6.
DOCKET# RP00–40, 000, NATIONAL FUEL GAS SUPPLY CORPORATION
CAG–7.
OMITTED
CAG–8.
OMITTED
CAG–9.
DOCKET# RP00–56, 000, NORTHWEST PIPELINE CORPORATION
CAG–10.
DOCKET# RP00–36, 000, EAST TENNESSEE NATURAL GAS COMPANY
CAG–11.
OMITTED
CAG–12.
DOCKET# RP00–52, 000, SOUTHERN NATURAL GAS COMPANY
CAG–13.
DOCKET# RP00–30, 000, ANR PIPELINE COMPANY
CAG–14.
DOCKET# RP00–46, 000, YOUNG GAS STORAGE COMPANY, LTD.
CAG–15.
DOCKET# RP00–39, 000, NATURAL GAS PIPELINE COMPANY OF AMERICA
CAG–16.
OMITTED
CAG–17.
DOCKET# RP00–45, 000, ANR PIPELINE COMPANY
CAG–18.
DOCKET# RP00–23, 000, SOUTHERN NATURAL GAS COMPANY, SOUTH GEORGIA NATURAL GAS COMPANY, DESTIN PIPELINE COMPANY, L.L.C. AND SEA ROBIN PIPELINE COMPANY
OTHER#S RP00–25, 000, NATURAL GAS PIPELINE COMPANY OF AMERICA, KN INTERSTATE GAS TRANSMISSION COMPANY, KN WATTENBERG TRANSMISSION, LIMITED LIABILITY COMPANY, CAPROCK PIPELINE COMPANY, CANYON CREEK COMPRESSION COMPANY, STINGRAY PIPELINE COMPANY, TRAILBLAZER PIPELINE COMPANY AND TCP GATHERING COMPANY
RP00–26, 000, TRANSCOLORADO GAS COMPANY
RP00–31, 000, COLUMBIA GAS TRANSMISSION COMPANY AND COLUMBIA GULF TRANSMISSION COMPANY
RP00–48, 000, IROQUOIS GAS TRANSMISSION SYSTEMS, L.P.
RP00–49, 000, KOCH GATEWAY PIPELINE COMPANY
CAG–19.
DOCKET# RP00–34, 000, TEXAS EASTERN TRANSMISSION CORPORATION
CAG–20.
DOCKET# RP00–50, 000, TEXAS EASTERN TRANSMISSION CORPORATION
CAG–21.
DOCKET# RP00–24, 000, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
OTHER#S RP00–24, 001 TRANSCONTINENTAL GAS PIPE LINE CORPORATION
CAG–22.
DOCKET# RP00–33, 000, MICHIGAN GAS STORAGE COMPANY
CAG–23.
DOCKET# RP00–57, 000, COLORADO INTERSTATE GAS COMPANY
CAG–24.
DOCKET# RP00–42, 000, ALGONQUIN GAS TRANSMISSION COMPANY
CAG–25.
DOCKET# PR99–18, 000, NORTHERN ILLINOIS GAS COMPANY
CAG–26.
OMITTED
CAG–27.
DOCKET# RP00–28, 000, FLORIDA GAS TRANSMISSION COMPANY
CAG–28.
DOCKET# RP00–54, 000, SOUTH GEORGIA NATURAL GAS COMPANY
CAG–29.
DOCKET# RP96–312, 018, TENNESSEE GAS PIPELINE COMPANY
OTHER#S RP96–312, 019, TENNESSEE GAS PIPELINE COMPANY
RP96–312, 020, TENNESSEE GAS PIPELINE COMPANY
RP96–312, 021, TENNESSEE GAS PIPELINE COMPANY
RP96–312, 022, TENNESSEE GAS PIPELINE COMPANY
CAG–30.
DOCKET# RP00–55, 000, TENNESSEE GAS PIPELINE COMPANY
CAG–31.
DOCKET# RP96–129, 000, TRUNKLINE GAS COMPANY
CAG–32.
DOCKET# RP93–5, 035, NORTHWEST PIPELINE CORPORATION
OTHER#S RP93–96, 014, NORTHWEST PIPELINE CORPORATION
CAG–33.
DOCKET# RP97–307, 005, ANR PIPELINE COMPANY
OTHER#S RP97–367, 003, ANR PIPELINE COMPANY
CAG–34.
DOCKET# CP93–736, 009, COLUMBIA GAS TRANSMISSION CORPORATION
CAG–35.
DOCKET# RP99–431, 001, KOCH GATEWAY PIPELINE COMPANY
CAG–36.
DOCKET# RP99–381, 002, WYOMING INTERSTATE COMPANY, LTD.
CAG–37.
OMITTED
CAG–38.

OMITTED
CAG–39.
DOCKET# RP97–71, 012, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
OTHER#S RP95–197, 034, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
CAG–40.
DOCKET# MG99–26, 000, DAUPHIN ISLAND GATHERING PARTNERS
CAG–41.
DOCKET# CP99–241, 000, ANR PIPELINE COMPANY
CAG–42.
DOCKET# CP96–27, 005, NATURAL GAS PIPELINE COMPANY OF AMERICA
CAG–43.
DOCKET# CP98–131, 002, VECTOR PIPELINE L.P.
OTHER#S CP98–133, 002, VECTOR PIPELINE L.P.
CP98–133, 003, VECTOR PIPELINE L.P.
CP98–134, 002, VECTOR PIPELINE L.P.
CP99–135, 002, VECTOR PIPELINE L.P.
CAG–44.
DOCKET# CP98–529, 001, PACIFIC INTERSTATE TRANSMISSION COMPANY
OTHER#S RP98–247, 001, NORTHWEST ALASKAN PIPELINE COMPANY
RP98–370, 001, NORTHWEST PIPELINE COMPANY
CP98–603, 002, NORTHWEST ALASKAN PIPELINE COMPANY
CP98–690, 001, PG&E GAS TRANSMISSION, NORTHWEST CORPORATION, TRANSWESTERN PIPELINE COMPANY, PACIFIC INTERSTATE TRANSMISSION COMPANY AND PAN–ALBERTA GAS (U.S.) INC.
CP98–738, 001, NORTHWEST PIPELINE COMPANY

Hydro Agenda

H–1.
RESERVED

Electric Agenda

E–1. RESERVED

Oil and Gas Agenda

I. PIPELINE RATE MATTERS
PR–1.
OMITTED
II.
PIPELINE CERTIFICATE MATTERS
PC–1.
DOCKET# CP97–315, 000, INDEPENDENCE PIPELINE COMPANY
OTHER#S CP97–315, 001, INDEPENDENCE PIPELINE COMPANY
CP97–319, 000, ANR PIPELINE COMPANY
CP97–320, 000, INDEPENDENCE PIPELINE COMPANY
CP97–321, 000, INDEPENDENCE PIPELINE COMPANY
CP98–200, 000, NATIONAL FUEL GAS SUPPLY CORPORATION
CP98–540, 000, TRANSCONTINETAL GAS PIPE LINE CORPORATION

Order on Application for Pipeline Certificate.

David P. Boergers,

Secretary.

[FR Doc. 99–30362 Filed 11–17–99; 1:11 pm]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6478–4]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance Manual and Example NPDES Permit for Concentrated Animal Feeding Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit the following proposed Information Collection Request (ICR) to the Office of Management and Budget (OMB): Guidance Manual and Example NPDES Permit for Concentrated Animal Feeding Operations, ICR 1937.01. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before January 18, 2000.

ADDRESSES: All public comments shall be submitted to: Charlotte White, Office of Wastewater Management, MC 4203, U.S. EPA Headquarters, 401 M Street, SW, Washington, DC 20460. Interested persons may obtain a copy of the proposed ICR without charge by calling or writing to Charlotte White at the Office of Wastewater Management, MC 4203, U.S. EPA Headquarters, 401 M Street, SW, Washington, DC 20460; telephone: (202) 260–8559.

FOR FURTHER INFORMATION CONTACT: Charlotte White, telephone: (202) 260–8559, fax: (202) 260–1460, E-mail: white.charlotte@epa.gov

SUPPLEMENTARY INFORMATION: *Affected entities*: Entities potentially affected by this action are defined as concentrated animal feeding operations (''CAFOs'' which are point sources subject to permitting under the National Pollutant Discharge Elimination System (NPDES)), EPA, and NPDES-authorized States implementing the NPDES permitting program for CAFOs.

Title: Guidance Manual and Example NPDES Permit for Concentrated Animal Feeding Operations; EPA ICR No. 1937.01

Abstract: This information collection burden is a result of EPA's planned issuance of guidance to National Pollutant Discharge Elimination System (NPDES) program authorized permitting authorities concerning permits issued to concentrated animal feeding operations (CAFOs). The animal livestock industry is undergoing a dramatic change with a shift towards larger facilities and increased potential for water quality impacts. To help address this change and the potential and actual impacts on water quality, the guidance manual is intended to provide clear and concise guidance for permitting agencies regarding the development of effective NPDES permits for CAFOs. The guidance does not increase the number of CAFOs subject to permitting under the NPDES permitting program, however, it recommends the development of a comprehensive nutrient management plan (CNMP) as a special condition of NPDES permits issued to CAFOs. This proposed ICR covers the development of the CNMP, which includes soil and manure sampling; reporting of CNMP development to the permitting authority; and other reporting and record keeping activities that are not described in the current NPDES program guidance for CAFOs. Components of a CNMP typically include: manure handling and storage, land application of manure, land management, record keeping, and other utilization options. EPA believes this CNMP will reduce the potential impact that this change in industry will have on water quality. CNMP data will be used by EPA and States to develop permits, used by the regulated facilities to ensure appropriate land application, and used by the compliance monitoring and enforcement personnel to document compliance. The guidance also recommends that the permittee maintain records concerning manure generation and disposition, and summarize this information on an annual reporting form. Under the guidance the permittee would also be asked to certify that the facility's CNMP reflects current conditions. EPA needs this information to more fully and effectively implement the requirements of the Clean Water Act, which prohibits the discharge of pollutants from point sources—including discharges from CAFOs—to U.S. waters without an NPDES permit.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control

numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Burden Statement: EPA estimates that the average annual burden for this ICR is 1,091,445 hours for CAFO respondents (i.e., facilities that may be required to apply for and obtain an NPDES permit), 92,400 hours for States authorized to implement the NPDES permitting program for CAFOs, and 447 hours for Federal agencies. The estimated total number of CAFO respondents over the reporting period is 9,145. This ICR covers a three-year period and the number of respondents per year is phased in at approximately 20 percent in the first year, 40 percent in the second year, and 40 percent in the third year, yielding an annual average number of CAFO respondents of 5,487. Based on this annual average, EPA estimates that there will be 10,974 responses per year, some of which represent one-time responses while others occur annually after CNMP development has been completed. EPA estimates that the average burden per response will be 99 hours, although the burden to develop CNMPs will be larger than the burden for reporting activities. Average total annual O&M costs for manure and soil samples is $665,373 for all respondents; there are no capital costs associated with this ICR. Table 1 summarizes these and other details of the ICR burden and cost estimates.

TABLE 1.—SUMMARY OF BURDEN AND COSTS FOR THE GUIDANCE MANUAL AND EXAMPLE NPDES PERMIT FOR CONCENTRATED ANIMAL FEEDING OPERATIONS INFORMATION COLLECTION REQUEST

Category	Burden or cost
CAFO Burden by Response:	
—One-time CNMP Development Burden (hours) (A)	1,025,072
—One-time CNMP Development Notification Burden (hours) (B)	3,048
—Annual CNMP Certification Burden (hours) (C)	2,439
—Annual Record Keeping Burden (hours) (D)	60,887
Total Annual CAFO Response Burden (hours) (A+B+C+D)	1,091,445
Annual Manure/soil Sample Cost ($)	$665,373
Annual Number of Responses (E)	10,974
Average Burden per Response (hours) (A+B+C+D)/(E)	99
Annual State Burden (hours)	92,400
Annual Federal Burden (hours)	447

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: November 15, 1999.

Alfred Lindsey,

Deputy Director, Office of Wastewater Management.

[FR Doc. 99–30234 Filed 11–18–99; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6248–2]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information, (202) 564–7167 or www.epa.gov/oeca/ofa.

Weekly receipt of Environmental Impact Statements filed November 08, 1999 through November 12, 1999 pursuant to 40 CFR 1506.9.

EIS No. 990423, Final EIS, NPS, NB, Homestead National Monument of America, General Management Plan, Implementation, Gage County, NB, Due: December 20, 1999, Contact: Michael Madell (608) 264–5257.

EIS No. 990424, Draft EIS, FHW, FL, FL–423 (John Young Parking), Improvements from FL–50 to Fl–434, City of Orlando, Orange County, FL, Due: January 04, 2000, Contact: Mark Bartlett (850) 942–9650.

EIS No. 990425, Draft EIS, SFW, AK, Wolf Lake Area Natural Gas Pipeline Project, Construction, Approval Right-of-Way Grant and COE Section 404 Permit, Kenai National Wildlife Refuge, AK, Due: January 18, 2000, Contact: Brian L. Anderson (907) 786–3379.

EIS No. 990426, Draft EIS, USA, CA, Oakland Army Base Disposal and Reuse Plan, Implementation, City of Oakland, Alameda County, CA, Due: January 03, 2000, Contact: Theresa Persick Arnold (703) 697–0216.

EIS No. 990427, Final EIS, NPS, CA, Redwood National and State Parks General Management Plan, Implementation, Humboldt and Del Norte Counties, CA, Due: December 20, 1999, Contact: Alan Schmierer (415) 427–1441.

EIS No. 990428, Final EIS, FRC, IL, MI, PA, IN, OH, NJ, Independence Pipeline and Market Link Expansion Projects, Construction and Operation, Interstate National Gas Pipeline, (Docket Nos. CP97–315–001, CP97–319–000, CP98–200–000 and CP98–540–000), NPDES and COE Section 404 Permits, IL, IN, MI, OH, PA and NJ, Due: December 20, 1999, Contact: Paul McKee (202) 208–1088.

EIS No. 990429, Draft EIS, FRC, MT, ID, Cabinet Gorge (No. 2058–014) and Noxon Rapids (No. 2075–014) Hydroelectric Project, Relicensing, MT and ID, Due: January 03, 2000, Contact: Bob Easton (202) 219–2782.

EIS No. 990430, Draft EIS, COE, AZ, Rio de Flag Flood Control Study, Improvement Flood Protection, City of Flagstaff, Coconino County, AZ, Due: January 04, 2000, Contact: David Compas (213) 452–3850.

EIS No. 990431, Draft EIS, FHW, OH, Meigs–124–21.16 Transportation Corridor, Relocating existing OH–124 and US 33, Meigs County, OH, Due: January 10, 2000, Contact: Timothy M. Hill (614) 644–0377.

EIS No. 990432, Final EIS, AFS, CO, Arapahoe Basin Ski Area Master Development Plan, Construction and Operation, COE Section 404 Permit, White River National Forest, Dillon Ranger District, Summit County, CO, Due: December 20, 1999, Contact: Michael Liu (970) 468–5400.

EIS No. 990433, Draft EIS, FTA, CA, Vasona Corridor Light Rail Transit Project, Extension of existing Light Rail Transit (LRT), in portion of the Cities of San Jose, Campbell and Los Gatos, Santa Clara County, CA, Due: January 03, 2000, Contact: Jerome Wiggins (415) 744–3115.

EIS No. 990434, Final EIS, DOE, CA, NM, TX, ID, SC, WA, Surplus Plutonium Disposition (DOE/EIS–0283) for Siting, Construction and Operation of three facilities for Plutonium Disposition, Possible Sites Hanford, Idaho National Engineering and Environmental Laboratory, Pantex Plant and Savannah River, CA, ID, NM, SC, TX and WA, Due: December 20, 1999, Contact: G. Bert Stevenson (202) 586–5368.

Dated: November 16, 1999.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 99–30289 Filed 11–18–99; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6248–3]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared November 01, 1999 through November 05, 1999 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 10, 1999 (63 FR 17856).

Draft EISs

ERP No. D–AFS–J65312–WY—Rating EO2, Squirrel Meadows—Grand Targhee Land Exchange Proposal, Implementation, Targhee National Forest, Teton County, WY.

Summary: EPA has environmental concerns about the lack of analysis on the direct and indirect impacts to wetlands and wildlife habitat from the additional development in proposed alternatives B, C, and D. Because the land exchange and resulting base area development are ''connected actions'' EPA believe a more detailed environmental analysis is required.

ERP No. D–AFS–K65219–CA—Rating EC2, Eldorado and Tahoe National Forests Land and Resource Management Plan, Standard and Guidelines for the Grazing Allotments, Implementation, CA.

Summary: EPA expressed environmental concerns with the potential resource shortfalls that might prevent monitoring and restoration activities as well as a lack of mandatory reductions in AUMs, elimination of grazing on specific allotments, or the triggering of additional protections when monitoring goals are not achieved.

ERP No. D–AFS–L65332–OR—Rating LO, Ashland Creek Watershed Protection Project, Proposal to Manage Vegetation, Rogue River National Forest, Ashland Ranger District, City of Ashland, Jackson County, OR.

Summary: EPA Region 10 used a screening tool to conduct a limited review of this action. Based upon the screen, EPA does not foresee having any environmental objections to the proposed project.

ERP No. D–FAA–A52169–00—Rating LO, Programmatic EIS—Commercial Launch Vehicles, Implementation, Issuing a Launch License.

Summary: EPA had no objection to the proposed action, although some text clarification suggestion were provided.

ERP No. D–FHW–J40151–WY—Rating EC2, Wyoming Forest Highway 23 Project, Louis Lake Road also known as Forest Development Road 300, Improvements from Bruce's Parking Lot to Worthen Meadow Road, Funding, NPDES Permits and COE Section 404 Permit, Shoshone National Forest, Fremont County, WY.

Summary: EPA expressed environmental concerns regarding the analysis of cumulative/indirect impacts and the range of alternatives. EPA requested that mitigation be included to reduce erosion and sedimentation of adjacent water and also requested additional information on alternatives for the existing roadway and potential cumulative effects to wildlife in the Forest.

ERP No. D–FRC–L05220–WA—Rating EC2, Warm Creek (No. 10865) and Clearwater Creek (No. 11485) Hydroelectric Project, Issuance of License for the Construction and Operation, Located in the Middle Fork Nooksack River (MFNR) Basin, WA.

Summary: EPA expressed concerns over the purpose and need for the projects, given their very small size; potential impacts to salmonids in the event of access above the Middle Fork Nooksack River diversion dam, which is downstream from the projects; and a lack of a true cost benefit analysis.

ERP No. DS–FHW–G50008–00—Rating EC2, Great River Bridge, Construction, US 65 in Arkansas to MS–8 in Mississippi, Funding, COE Section 404 Permit and US Coast Guard Bridge Permit, Desha and Arkansas Counties, AR and Bolivar County, MS.

Summary: EPA expressed environmental concerns regarding wetland and wildlife habitat impacts and the mitigation of these impacts. EPA requested that additional information be provided on these issues in the next document.

Final EISs

ERP No. F–AFS–L60106–ID, Long Prong Project, Timber Harvesting, Road Construction and Reconstruction, Boise National Forest, Cascade Ranger District, Valley County, ID.

Summary: No formal comment letter sent to the lead agency.

ERP No. F–AFS–L65290–ID, North Lochsa Face Landscape and Watershed Assessment Project, Implementation, Clearwater National Forest, Lochsa Ranger District, Idaho County, ID.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–AFS–L65303–WA, I–90 Land Exchange between Forest Service and Plum Creek, within the Vicinity of the Wenatchee, Mt. Baker-Snoqualmie and Gifford Pinchot National Forests, Kittitas, King, Pierce, Lewis, Cowlitz and Skamania Counties, WA.

Summary: EPA expressed lack of objections.

ERP No. F–COE–L32010–OR, Columbia and Lower Willamette River Federal Navigation Channel,

Improvement Channel Deepening, OR and WA.

Summary: EPA's previous concerns have been addressed, therefore EPA has no objection to the proposed action.

ERP No. F–FHW–F40375–IL, IL–315 Federal Aid Primary (FAP) (Illinois-336) Transportation Project, Construction from FAP 315, IL 336 (Southeast of Carthage) to US 136 (Just West of Macomb), Funding, COE 404 Permit and NPDES Permit, Hancock and McDonough Counties, IL.

Summary: EPA's previously expressed concerns for documentation of wetlands avoidance/minimization and identification of a satisfactory conceptual wetlands compensation plan have been resolved. Therefore, EPA has no objections to the action as proposed.

ERP No. F–FHW–F40381–MN, Phalen Boulevard Project, Construction of a new 4.3 Kilometer Roadway, from I35E to Johnson Parkway, Funding, in the City of St. Paul, Ramsey County, MN.

Summary: Final EIS provided adequate information and analysis to address EPA's previous environmental concerns, therefore, EPA has no objection to the proposed action.

ERP No. F–NOA–B91026–ME, Atlantic Herring (Clupea harengus harengus) Fishery Management Plan (FWP), Management Measures, Exclusive Ecosystem Zone (EEZ), Gulf of Maine, George Bank, ME.

Summary: EPA had no objections to the project.

ERP No. F–NOA–B91027–00, Spiny Dogfish (Squalus acanthras) Fishery Management Plan, Implementation, Northwest Atlantic Ocean, Labrador to Florida.

Summary: EPA had no objection to the project and offered general comments with respect to ghost fishing and the characterization of ocean disposal issues.

ERP No. F–NPS–K61123–CA, Backcounty and Wilderness Management Plan, General Management Plan Amendment, Joshua Tree National Park, Riverside and San Bernardino Counties, CA.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–NPS–L61160–AK, Lower Sheenjek River Wild/Scenic River Study, Designation or Non-Designation for Inclusion in the National Wild and Scenic River System, Tributary of the Porcupine River, Yukon Flats National Wildlife Refuge, AK.

Summary: No formal comment letter sent to the preparing agency.

Dated: November 16, 1999.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 99–30290 Filed 11–18–99; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6479–1]

Science Advisory Board; Notification of Public Advisory Committee Meeting

Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that the Environmental Models Subcommittee (EMS) of the Science Advisory Board's (SAB) Executive Committee, will meet Monday and Tuesday December 13 and 14, 1999 in the Environmental Research Center (ERC) Classroom No. 2, Highway 54 & Alexander Drive, at the U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. The meeting will begin at 9:00 am on December 13 and adjourn no later than 5:00 pm on December 14th (Eastern Time). This meeting is open to the public, however, seating is limited and available on a first come basis. Documents that are the subject of SAB reviews are normally available from the originating U.S. Environmental Protection Agency (EPA) office and are *not* available from the SAB Office. Public drafts of SAB reports are available to the Agency and the public from the SAB office. Details on availability are noted below.

Purpose

The purpose of this meeting is to: (a) Conduct an advisory on the Agency's Total Risk Integrated Methodology (TRIM) as part of a continuing review of this modeling system which is being developed by the Office of Air and Radiation (OAR), Office of Air Quality Planning and Standards (OAQPS) to support the Agency's regulatory decision making for air pollutants; (b) receive an update and briefing on the workplan for implementation of activities of the Council for Regulatory Environmental Modeling (CREM); and (c) conduct planning for the Fiscal Year 2000 activities of the Environmental Models Subcommittee (EMS) of the Science Advisory Board (SAB), such as a possible future review of the MINTEQA2 model.

SAB Advisory on TRIM

The Agency's OAR is developing TRIM which is intended to support the Agency's regulatory decision making for air pollutants. The intent in creating TRIM with a flexible framework using open architecture is that it will provide the Agency with essential multi-media, multi-pathway air pollutant modeling capabilities in the short term, as well as allow the Agency to take advantage of future advances made over the longer term modeling and monitoring research. The basic charge questions the Agency is raising to the SAB's EMS deal with the overall TRIM system, as well as the three individual modules. The charge questions on the overall TRIM system deal with the TRIM's current design, modular approach, and open architecture, as well as the scientific reasonableness of plans for addressing uncertainty and variability. Questions are being asked by the Agency to the SAB's EMS regarding improvements in the ability of TRIM.FaTE to incorporate outputs from external models, to model chemical transformation and metals, and to incorporate seasonal processes. An additional question is focused on issues associated with the incorporation of both horizontal and vertical atmospheric dispersion and diffusion algorithms, as well as what alternate methods might be recommended to incorporate these algorithms. The SAB's EMS will also be asked to critique an evaluation plan for TRIM.FaTE. In addition, questions are being raised with regard to the adequacy of the TRIM.Expo proposed conceptual design and specific algorithms chosen in the modeling framework, as well as the adequacy of the conceptual plan for the TRIM.Risk module.

The SAB's EMS will also be updated on the activities and work plan for implementation of the Committee for Environmental Regulatory Modeling (CREM).

For Further Information

Copies of the review documents and any background materials for the review are *not available* from the SAB. The TRIM review documents are available from the program office by contacting Dr. Deirdre Murphy by telephone at (919) 541–0729; by fax at (919) 541–0237, or by E-mail at <*murphy.deirdre@epa.gov*>. The documents that are being provided to the SAB's EMS include the following: (1) TRIM Status Report, (2) TRIM.FaTE Technical Support Document, Vol. I, (3) TRIM.FaTE Technical Support Document, Vol. II, and (4) TRIM.EXPO Technical Support Document. The CREM update will be available to the Subcommittee as well as to members of the public at the meeting. You may call, fax or E-mail the program office for information regarding the status of

CREM by contacting Mr. Johnnie Pearson by telephone at (919) 541–0572; by fax at (919) 541–0445; or by e-mail at <*pearson.johnnie@epa.gov*> to obtain the update materials when they are available.

Any member of the public wishing further information concerning the meeting should contact Dr. K. Jack Kooyoomjian, Designated Federal Officer for the Environmental Models Subcommittee, Science Advisory Board (1400A), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460 at (202) 564–4557; by fax (202) 501–0582; or by E-mail at <*kooyoomjian.jack@epa.gov*>. Anyone wishing to make an oral presentation at the meeting must contact Dr. Kooyoomjian *in writing* no later than close of business Tuesday, December 7, 1999, at the above address, fax or e-mail. The request should identify the name of the individual who will make the presentation and an outline of the issues to be addressed. Copies of the draft meeting agenda are available from Ms. Dorothy Clark, Management Assistant, Committee Operations Staff at (202) 564–4537; by fax at (202) 501–0582; or by E-mail at <*clark.dorothy@epa.gov*>.

Providing Oral or Written Comments at SAB Meetings

The Science Advisory Board expects that public statements presented at its meetings will not repeat previously submitted oral or written statements. In general, each individual or group making an oral presentation will be limited to a total time of ten minutes. This time may be reduced at the discretion of the SAB, depending on meeting circumstances. Oral presentations at teleconferences will normally be limited to three minutes per speaker or organization. Written comments (at least 35 copies) received in the SAB Staff Office sufficiently prior to a meeting date, may be mailed to the relevant SAB committee or subcommittee prior to its meeting; comments received too close to the meeting date will normally be provided to the committee at its meeting. Written comments, which may be of any length, may be provided to the relevant committee or subcommittee up until the time of the meeting.

Information concerning the Science Advisory Board, its structure, function, and composition, may be found in The Annual Report of the Staff Director which is available from the SAB Committee Evaluation and Support Staff (CESS) by contacting US EPA, Science Advisory Board (1400A), Attention: CESS, 401 M Street, SW, Washington, DC 20460 or via fax (202) 501–0256. Additional information concerning the SAB can be found on the SAB Home Page at: http://www.epa.gov/sab.

Meeting Access

Individuals requiring special accommodation at this meeting, including wheelchair access, should contact the appropriate DFO at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: November 10, 1999.

Donald G. Barnes,

Staff Director, Science Advisory Board.

[FR Doc. 99–30240 Filed 11–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–30485; FRL–6392–7]

Pesticide Products; Registration Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application to register a pesticide product containing a new active ingredient not included in any previously registered product pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments, identified by the docket control number OPP–30485, must be received on or before December 20, 1999.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA. It is imperative that you identify docket control number OPP–30485 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Ann Sibold, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703 305–6502; and e-mail address: sibold.ann@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS), codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–30485. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is

available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–30485 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: ''opp-docket@epa.gov,'' or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.1 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–30485. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the ''FOR FURTHER INFORMATION CONTACT.''

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the registration activity.

7. Make sure to submit your comments by the deadline in this notice.

8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Registration Application

EPA received an application as follows to register a pesticide product containing an active ingredient not included in any previously registered product pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of this application does not imply a decision by the Agency on the application.

File Symbol: 241–GTU. *Applicant*: American Cyanamid Company, Agricultural Research Division, P.O. Box 400 Princeton, NJ 08543–0400. *Product Name*: Alert insecticide miticide. *Active Ingredient*: 4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1*H*-pyrrole-3-carbonitrile at 21.4%. *Proposed classification/Use*: For use on ornamental crops grown in commercial greenhouses to control spider mites, including two-spotted spider mite; worm pests, including beet armyworm, cabbage looper, and soybean looper; thrips, including western flower thrips; and greenhouse whiteflies.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: November 4, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 99–30242 Filed 11–18–99; 8:45 am]
BILLING CODE 6560–50–F

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–3140–EM]

California; Amendment No. 6 to Notice of an Emergency

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency for the State of California, (FEMA–3140–EM), dated September 1, 1999, and related determinations.

EFFECTIVE DATE: November 12, 1999.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3772.

SUPPLEMENTARY INFORMATION: The notice of an emergency for the State of California is hereby amended to include disaster housing as authorized under subsection 502(a)(6) for the following areas among those areas determined to have been adversely affected by the catastrophe declared an emergency by the President in his declaration of September 1, 1999:

The counties of Butte, San Bernardino, Shasta, and Yuba for disaster housing as authorized under subsection 502(a)(6) (already designated for emergency protective measures, including the limited removal of debris which poses a health and safety hazard to the general public, as authorized under Title V.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing

Program; 83.548, Hazard Mitigation Grant Program.)

James L. Witt,

Director.

[FR Doc. 99–30254 Filed 11–18–99; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1295–DR]

New Jersey; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of New Jersey, (FEMA–1295–DR), dated September 18, 1999, and related determinations.

EFFECTIVE DATE: November 9, 1999.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3772.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of New Jersey is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of September 18, 1999:

Hunterdon County for Categories C through G under the Public Assistance program (already designated for Categories A and B under Public Assistance and Individual Assistance).

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program.)

Lacy E. Suiter,

Executive Associate Director, Response and Recovery Directorate.

[FR Doc. 99–30252 Filed 11–18–99; 8:45 am]

BILLING CODE 6718–02–V

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1307–DR]

Vermont; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Vermont (FEMA–1307–DR), dated November 10, 1999, and related determinations.

EFFECTIVE DATE: November 10, 1999.

FOR FURTHER INFORMATION CONTACT: Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3772.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated November 10, 1999, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:

I have determined that the damage in certain areas of the State of Vermont, resulting from severe storms and flooding associated with Hurricane Floyd on September 16–21, 1999, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub. L. 93–288, as amended (''the Stafford Act''). I, therefore, declare that such a major disaster exists in the State of Vermont.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation in the designated areas and any other forms of assistance under the Stafford Act you may deem appropriate. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance or Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Justo Hernandez of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Vermont to have been affected adversely by this declared major disaster:

Bennington, Caledonia, Essex, Lamoille, Orange, Orleans, Rutland, Washington, Windham, and Windsor Counties for Public Assistance.

All counties within the State of Vermont are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program.)

James L. Witt,

Director.

[FR Doc. 99–30253 Filed 11–18–99; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL MARITIME COMMISSION

[Docket No. 99–23]

In the Matter of a Single Individual Contemporaneously Acting as the Qualifying Individual for Both an Ocean Freight Forwarder and a Non-Vessel Operating Common Carrier; Notice of Filing of Petition for Declaratory Order or, in the Alternative, for Issuance of a Rulemaking

Notice is given that a petition for declaratory order, or, in the alternative, for issuance of a rulemaking, has been filed by the National Customs Brokers & Forwarders Association of America (''Petitioner'').

Petitioner requests that the Commission issue a declaratory order confirming that, pursuant to 46 CFR 515.11(c), a single individual can contemporaneously act as the qualifying individual in obtaining ocean transportation intermediary licenses for both an ocean freight forwarder and a non-vessel operating common carrier, if the two are affiliated entities. Alternatively, petitioner requests that the Commission amend 46 CFR 515.11(c), by revising the last sentence to read:

The qualifying individual of one active licensee shall not also be designated contemporaneously as the qualifying individual of an applicant for another ocean transportation intermediately license, unless the entities are affiliated and the person who

is to be the qualifying individual is an officer of both entities.

Interested persons may submit replies (an original and 15 copies) to the Secretary, Federal Maritime Commission, Washington, DC 20573 on or before December 10, 1999. [1] Replies must also be served on counsel for Petitioner: Edward D. Greenberg, Galland, Kharasch, Greenberg, Fellman & Swirsky P.C., 1054 31st St., NW, Washington, DC 20007. Replies shall contain the complete factual and legal presentation of the replying party as to the desired resolution of the petition, pursuant to 46 CFR 502.68(d).

Copies of the petition are available for examination at the Office of the Secretary, Federal Maritime Commission, 800 North Capitol St., N.W., Room 1046, Washington, DC.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 99–30287 Filed 11–18–99; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY:

Background. Notice is hereby given of the final approval of proposed information collection(s) by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the OMB 83-Is and supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT: Chief, Financial Reports Section--Mary M. West--Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202-452-3829); OMB Desk Officer--Alexander T. Hunt--Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503 (202-395-7860).

Discontinuation of the following report:

1. Report title: Commercial Bank Report of Consumer Credit.
Agency form number: FR 2571.
OMB Control number: 7100-0080.
Effective Date: Mid-year 2000.
Frequency: Monthly.
Reporters: Commercial Banks.
Annual reporting hours: 2,475 hours.
Estimated average hours per response: 33 minutes.
Number of respondents: 375 commercial banks.
Small businesses are affected.
General description of report: This information collection is voluntary (12 U.S.C. 248(a)(2)) and is given confidential treatment (5 U.S.C. 552(b)(4)).

Abstract: The FR 2571 collects information on outstanding consumer credit, by type, as of the last business day of the month, from a sample of commercial banks. This survey, however, has become less reliable in recent years. Sales of loan portfolios between banks inside and outside of the FR 2571 sample cause the estimated amount of consumer credit held or securitized by commercial banks to fluctuate sharply relative to that held or securitized by the commercial bank universe. Extensive ad hoc adjustments are often needed to keep the consumer credit data in what is believed to be a reasonable range. The accuracy of these adjustments is unknown until staff benchmark total commercial bank consumer credit to the quarterly Consolidated Reports of Condition and Income (Call Report; FFIEC 031-034).

Current Actions The Federal Reserve will discontinue the FR 2571as of mid-year 2000. Questions on revolving consumer loans and securitized total and revolving consumer loans were added to the bank credit reports: the Weekly Report of Assets and Liabilities for Large Banks (FR 2416), the Weekly Report of Selected Assets (FR 2644), and the Weekly Report of Assets and Liabilities for Large U.S. Branches and Agencies of Foreign Banks (FR 2069).

Final approval under OMB delegated authority of the extension for three years, with revision of the following reports:

1. Report title: Weekly Report of Assets and Liabilities for Large Banks.
Agency form number: FR 2416.
OMB control number: 7100-0075.
Effective Date: Mid-June 2000.
Frequency: Weekly.
Reporters: U.S.-chartered commercial banks.
Annual reporting hours: 18,850.
Estimated average hours per response: 7.25 hours.
Number of respondents: 50.
Small businesses are not affected.
General description of report: This information collection is voluntary (12 U.S.C.§§ 225(a) and 248(a)(2)) and is given confidential treatment (5 U.S.C. 552(b)(4)).

2. Report title: Weekly Report of Selected Assets.
Agency form number: FR 2644.
OMB control number: 7100-0075.
Effective Date: Mid-June 2000.
Frequency: Weekly.
Reporters: U.S.-chartered commercial banks.
Annual reporting hours: 66,924.
Estimated average hours per response: 1.17 hours.
Number of respondents: 1,100.
Small businesses are affected.
General description of report: This information collection is voluntary (12 U.S.C.§§ 225(a) and 248(a)(2)) and is given confidential treatment (5 U.S.C. 552(b)(4)).

3. Report title: Weekly Report of Assets and Liabilities for Large U.S. Branches and Agencies of Foreign Banks.
Agency form number: FR 2069.
OMB control number: 7100-0030.
Effective Date: Mid-June 2000.
Frequency: Weekly.
Reporters: U.S. branches and agencies of foreign (non-U.S.) banks.
Annual reporting hours: 27,891.
Estimated average hours per response: 5.83.
Number of respondents: 92.
Small businesses are not affected.
General description of report: This information collection is voluntary (12 U.S.C. 3105(b)(2)) and is given confidential treatment (5 U.S.C. 552(b)(4)).

Abstract: The FR 2416 is a detailed, 43-item balance sheet that covers domestic offices of large U.S.-chartered commercial banks. The FR 2644 collects 11 items covering investments and loans plus total assets and three memorandum items, two that disaggregate total borrowings between bank and nonbank sources and one for mortgage-backed securities. The FR 2069 is a detailed, 28-item balance sheet that covers large U.S. branches and agencies of foreign banks. These reports are collected as of each Wednesday.

These three voluntary reports are mainstays of the Federal Reserve's reporting system from which data for analysis of current banking developments are derived. The FR 2416

[1] In addition to the official paper filing, a party may also provide the Commission with a copy of its filing by diskette or by e-mail at Secretary@fmc.gov.

is used on a stand-alone basis as the ''large domestic bank series.'' The other two reports are samples for estimating outstandings for the universe, using data for benchmarks from the quarterly commercial bank Consolidated Reports of Condition and Income (FFIEC 031-034; OMB No. 7100-0036) and the Report of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks (FFIEC 002; OMB No.7100-0032) (Call Reports). All three reports, together with data from other sources, are used for constructing weekly estimates of bank credit, of sources and uses of bank funds, and of a balance sheet for the banking system as a whole. These estimates are used in constructing the bank credit component of the domestic nonfinancial debt aggregate.

The Federal Reserve publishes the data in aggregate form in a statistical release that is followed closely by other government agencies, the banking industry, the financial press, and other users. This weekly H.8 statistical release, ''Assets and Liabilities of Commercial Banks in the United States,'' provides a balance sheet for the banking industry as a whole and disaggregated by its large domestic, small domestic, and foreign related components

Current Actions: Effective mid-June 2000, the Federal Reserve will reduce the authorized size of the FR 2416 panel. Several reporters currently on the branch and agency (FR 2069) panel will be dropped because most of their assets have been shifted to other reporters.

The Federal Reserve will have a net addition of three items to the FR 2416 and the FR 2644; these three items were reported on the monthly Commercial Bank Survey of Consumer Credit (FR 2571; OMB No. 7100-0080). The Federal Reserve is discontinuing the FR 2571, which was contingent upon the addition of these items to the weekly condition/bank credit reports. The Federal Reserve also will add a memorandum item to the FR 2416 and the FR 2069 and clarify the FR 2416 and the FR 2644 instructions for reporting derivatives.

Final approval under OMB delegated authority of the extension for three years, without revision of the following reports:

1. Report title: The Recordkeeping and Disclosure Requirements Associated with Loans Secured by Real Estate Located in Flood Hazard Areas Pursuant to Section 208.25 of Regulation H.

Agency form number: unnum Reg H-2.

OMB control number: 7100-0280.

Frequency: Event-generated.

Reporters: State Member Banks.

Annual reporting hours: 58,885.

Estimated average hours per response: Notice of special flood hazards to borrowers and servicers, Notice to FEMA of servicer, and Notice to FEMA of change of servicer: 5 minutes each; Retention of standard FEMA form: 2.5 minutes.

Number of respondents: 988. Small businesses are affected.

General description of report: This information collection is mandatory (12 CFR 208.25). Since the Federal Reserve does not collect any information, no issue of confidentiality would normally arise. Should any of these records come into the possession of the Federal Reserve System, such information would be given confidential treatment (5 U.S.C. 552(b)(4) and (b)(6)).

Abstract: The regulation requires the state member banks (SMBs) to notify a borrower and servicer when loans secured by real estate are determined to be in a special flood hazard area. The SMB must then notify the borrower and servicer whether flood insurance is available. If a loan secured by real estate is in a special flood hazard area, the SMB must notify the Federal Emergency Management Agency (FEMA) of the identity of, and any change of, the servicer of the loan. Lastly, the SMB must retain a copy of the Standard Flood Hazard Determination Form used to determine whether the property securing a loan is in a special flood hazard area.

Board of Governors of the Federal Reserve System, November 15, 1999.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 99–30182 Filed 11–18–99; 8:45am]

Billing Code 6210–01–F

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 3, 1999.

A. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Guaranty Bancshares, Inc. Employee Stock Ownership Plan, Mount Pleasant, Texas; to retain additional voting shares of Guaranty Bancshares, Inc., Mount Pleasant, Texas, and thereby indirectly retain additional voting shares of Guaranty Bank, Mount Pleasant, Texas.

Board of Governors of the Federal Reserve System, November 15, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–30185 Filed 11–18–99; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 13, 1999.

A. Federal Reserve Bank of Atlanta (Cynthia Goodwin, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. Riverside Banking Company, Fort Pierce, Florida; to acquire 19.67 percent of Class A voting shares and 8.19 percent of Class B voting shares of The Prosperity Banking Company, St. Augustine, Florida, and thereby indirectly acquire Prosperity Bank of St. Augustine, St. Augustine, Florida.

2. Riverside Banking Company, Fort Pierce, Florida; to acquire 19.67 percent of Class A voting shares and 8.19 percent of Class B voting shares of Riverside Gulf Coast Banking Company, Cape Coral, Florida, and thereby indirectly acquire Riverside Bank of the Gulf Coast, Cape Coral, Florida.

Board of Governors of the Federal Reserve System, November 15, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–30186 Filed 11–18–99; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That Are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR part 225), to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 3, 1999.

A. Federal Reserve Bank of Chicago (Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. Bank One Corporation, Chicago, Illinois; to engage *de novo* through its subsidiary, One Group Administrative Services, Inc., Columbus, Ohio, in providing administrative services to Bank One's proprietary mutual funds, The One Group Mutual Funds and the One Group Investment Trust, and to other unaffiliated open-end and closed-end investment companies, *see Mellon Bank Corporation, Pittsburg, Pennsylvania, 79 Fed. Res. Bull. 626 (1993)* and *Barclays PLC, London, England, 82 Fed. Res. Bull. 158 (1996)* respectively.

Board of Governors of the Federal Reserve System, November 15, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–30183 Filed 11–18–99; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That Are Engaged in Permissible Nonbanking Activities; Correction

This notice corrects a notice (FR Doc. 99-29540) published on page 61645 of the issue for Friday, November 12, 1999.

Under the Federal Reserve Bank of New York heading, the entry for Deutsche Bank AG, Frankfurt (Main) Federal Republic of Germany, is revised to read as follows:

A. Federal Reserve Bank of New York (Betsy Buttrill White, Senior Vice President) 33 Liberty Street, New York, New York 10045-0001:

1. Deutsche Bank AG, Frankfurt (Main) Federal Republic of Germany; to engage *de novo* through DB Advisors L.L.C. (DB Advisors), New York, New York, in acting as a commodity pool operator for private limited partnerships and/or trusts (Investment Vehicles) organized as commodity pools which invest only in assets in which a bank holding company is permitted to invest, *See Dresdner Bank AG*, 84 Fed. Res. Bull. 361 (1998), and *UBS AG*, Letter, dated April 19, 1999, from the Federal Reserve Bank of New York; and to act as investment advisor to the Investment Vehicles, pursuant to § 225.28(b)(6) of Regulation Y; and to privately place equity interests in the Investment Vehicles with ''accredited investors'', pursuant to § 225.28(b)(7) of Regulation Y, *See Letter, dated February 13, 1998, to Troland S. Link, Esq., from Jay B. Bernstein, Federal Reserve Bank of New York*; and in providing administrative services to closed-end investment companies, *See Deutsche Bank AG*, 85 Fed. Res. Bull. 509 (1999). These activities will be conducted worldwide.

Comments on this application must be received by November 26, 1999.

Board of Governors of the Federal Reserve System, November 15, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–30184 Filed 11–18–99; 8:45 am]

BILLING CODE 6210–01–F

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

Government in the Sunshine Meeting Notice

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 10 a.m., Wednesday, November 24, 1999.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any matters carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: November 17, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–30348 Filed 11–17–99; 10:34 am]

BILLING CODE 6210–01–P

GENERAL ACCOUNTING OFFICE

Federal Accounting Standards Advisory Board

AGENCY: General Accounting Office.

ACTION: Notice of Meeting on December 13–14, 1999 and Announcement of Meeting Dates in 2000 for the Accounting and Auditing Policy Committee.

Board Meeting Summary

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92–463), as amended, notice is hereby given that the Federal Accounting Standards Advisory Board will hold a meeting on Thursday, December 13, and Friday, December 14, from 9:00 to 4:30 p.m. room 7C13, the comptroller General's Briefing Room, of the General Accounting Office building, 441 G St., NW, Washington, DC.

The purpose of the meeting is to discuss:

- National Defense PP&E
- Major Acquisition Program
- Required Supplementary Stewardship Information (RSSI)
- Technical Agenda Review
- Codification
- Accounting and Auditing Policy Committee Charter

Any interested person may attend the meeting as an observer. Board discussions and reviews are open to the public.

Announcement of Meeting Dates in 2000 for the Accounting and Auditing Policy Committee

Meetings are scheduled for:

January 20, 2000
March 9, 2000
May 11, 2000
July 13, 2000
September 14, 2000
November 9, 2000

Unless otherwise noted, all AAPC meetings will be in Room 4N30 at 441 G Street, NW, from 1:30 to 4:00 p.m.

FOR FURTHER INFORMATION, CONTACT: Wendy Comes, Executive Director, 441 G St., NW, Room 3B18, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act. Pub. L. No. 92–463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101–6.1015 (1990).

Dated: November 15, 1999.

Wendy M. Comes,

Executive Director.

[FR Doc. 99–30187 Filed 11–18–99; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research and Subcommittee for Community Affairs: Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following Federal advisory committee meetings.

Name: Advisory Committee for Energy-Related Epidemiologic Research (ACERER) Subcommittee for Community Affairs (SCA).

Times and Dates: 12:30 p.m.–6:45 p.m., December 13, 1999; 8:45 a.m.–5:15 p.m., December 16, 1999.

Place: Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, Virginia 22202, telephone 703/418–1234, fax 703/418–1289.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This subcommittee advises ACERER on matters related to community needs.

Matters To Be Discussed: Agenda items will include status of the Centers for Disease Control and Prevention (CDC) and the National Cancer Institute (NCI) follow-up to radio iodine fallout—risk communication to the American public; a panel discussion of adding doses and adding risks; and subcommittee input to the ACERER management review of the NCI Chernobyl studies.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Paul G. Renard, Executive Secretary, SCA, ACERER, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, M/S F–35, Atlanta, Georgia 30341–3724, telephone 770/488–7040, fax 770/488–7044.

Name: Advisory Committee for Energy-Related Epidemiologic Research (ACERER).

Times and Dates: 8:30 a.m.–5 p.m., December 14, 1999; 8:30 a.m.–4:30 p.m., December 15, 1999.

Place: Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, Virginia 22202, telephone 703/418–1234, fax 703/418–1289.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This committee is charged with providing advice and recommendations to the Secretary, HHS; the Assistant Secretary for Health, HHS; the Director, CDC; and the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), on establishment of a research agenda and the conduct of a research program pertaining to energy-related epidemiologic studies.

Matters To Be Discussed: Agenda items will include presentations from the Fred Hutchinson Cancer Research Center; the National Academy of Sciences; the Consortium for Risk Evaluation and Stakeholder Participation (CRESP); the Department of Energy on overall findings of their occupational medicine reviews; the National Institute for Occupational Safety and Health on the topic of notification and risk communication; a report on the status of the CDC report to Congress on fallout; a report from the ACERER Subcommittee for Management Review of the Chernobyl Studies; a report on the current status of CDC's research agenda and the current status of the revised Memorandum of Understanding; and relevant committee discussions.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Michael J. Sage, Executive Secretary, ACERER, and Acting Deputy Director, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, M/S F–28, Atlanta, Georgia 30341–3724, telephone 770/488–7300, fax 770/488–7310.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and ATSDR.

Dated: November 15, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 99–30204 Filed 11–18–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

The Division of Birth Defects, Child Development, and Disability and Health (DBDCH); Meeting

The Division of Birth Defects, Child Development, and Disability and Health (DBDCH) in the National Center for Environmental Health (NCEH) at the Centers for Disease Control and Prevention (CDC) announces the following conference.

Name: A conference entitled Infection in Pregnancy and Neurodevelopment.

Times and Dates: 7:30 a.m.–5 p.m., Nov. 30, 1999; 7:45 a.m.–3:45 p.m., Dec. 1, 1999.

Place: The Holiday Inn Select, Hotel and Conference Plaza, 130 Clairemont Avenue, Decatur, Georgia 30030.

Status: Open for participation by anyone with an interest in Public Health issues related to Infection in Pregnancy and Neurodevelopment, limited only by the space available. Persons wishing to participate must fax their request to (770) 488–7361 and indicate if they wish to attend.

Matters To Be Discussed: A large body of evidence suggests that infection, particularly subclinical infection, of the maternal reproductive tract during pregnancy is an important cause of premature birth. There is additional evidence suggesting that fetal infection may lead to brain damage and subsequent serious neurological impairment and disability, such as cerebral palsy. One of

the strategic goals of the Developmental Disabilities Branch (DDB) is to investigate causal factors for cerebral palsy and other serious neurodevelopmental disabilities for the purposes of prevention. The proposed workshop, organized by the DDB, National Center for Environmental Health, in collaboration with the National Center for HIV, STD and TB Prevention National Center for Infectious Diseases, and the National Center for Chronic Disease Prevention and Health Promotion, is designed to assist in the development of a prevention research agenda concerning the role of maternal/fetal infection during pregnancy, especially subclinical infection, on subsequent adverse neurodevelopmental outcomes of affected offspring. The agenda would guide extramural research activities by establishing research priorities and providing a research framework for CDC's extramural partners in the area of infection in pregnancy and neurodevelopment.

Contact Persons for More Information: Diana E. Schendel, Ph.D., telephone (770) 488–7359, or Marilyn Deal, telephone (770) 488–7695, Division of Birth Defects, Child Development, and Disability and Health (DBDCH), NCEH, CDC, 4770 Buford Highway, NE, Mailstop F–15, Atlanta, Georgia 30341. Fax (770) 488–7361.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 15, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 99–30203 Filed 11–18–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1109]

Mercury Compounds in Drugs and Food; List and Analysis; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Mercury Compounds in Drugs and Food.'' The document discusses drugs (including biologics) and foods that contain intentionally introduced mercury compounds. In addition, for those products that contain intentionally introduced mercury compounds, the document provides a quantitative and qualitative analysis of the mercury compounds in the products. This document has been prepared in response to the Food and Drug Administration Modernization Act of 1997 (FDAMA), section 413, entitled ''Food and Drug Administration Study of Mercury Compounds in Drugs and Food.''

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the document entitled ''Mercury Compounds in Drugs and Food'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Copies of the document are available on the Internet at http://www.fda.gov/cder/index.htm. Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For human drug products: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

For human biological products: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

For veterinary drug products: William C. Keller, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6641.

For food and dietary supplement products: Sharon A. Ross, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5343.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Mercury Compounds in Drugs and Food.'' This document discusses drugs (including biologics) and foods that contain intentionally introduced mercury compounds. In addition, for those products that contain intentionally introduced mercury compounds, the document provides a quantitative and qualitative analysis of the mercury compounds in the products.

This document is part of FDA's implementation of FDAMA (Public Law 105–115), enacted on November 21, 1997. Section 413 of FDAMA required FDA to: (1) Compile a list of drugs and foods that contain intentionally introduced mercury compounds, and (2) provide a quantitative and qualitative analysis of the mercury compounds in this list. FDAMA required the agency to compile the list and provide the analysis within 2 years after the date of its enactment.

The statute did not differentiate whether the mercury compound was present in a product as an active or inactive ingredient, whether the product was for human or veterinary use, or whether the product was sold by prescription or over-the-counter. Food products include dietary supplements.

In the **Federal Register** of December 14, 1998 (63 FR 68775) and April 29, 1999 (64 FR 23083), FDA published notices requesting data and information on any intentionally introduced mercury compounds in these types of products. The agency asked manufacturers of affected products to provide: (1) The commercial name of the product that contains the mercury compound; (2) the chemical name, quantitative amount, and purpose of the mercury compound present; (3) a copy of the product's labeling; and (4) an estimate of the amount of the mercury compound used annually in manufacturing the product.

The agency received 41 responses to the two request-for-data notices. The agency also reviewed information contained in its Drug Registration and Listing System and other sources to identify additional products that contain intentionally introduced mercury compounds. The document discusses the information that the agency reviewed and provides a list and analysis of the products that were identified. The document is intended to provide information and does not set forth any requirements.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments may be seen in the Dockets Management Branch between 9

a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–30214 Filed 11-18-99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 13, 1999, 9 a.m. to 5:30 p.m. and December 14, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 13, 1999, the committee will discuss: (1) New drug application (NDA) 21–055, Targretin® (bexarotene) Capsules, 75 milligrams, Ligand Pharmaceuticals, Inc., indicated for the treatment of patients with all clinical stages (IA–IVB) of cutaneous T-cell lymphoma (CTCL) in the following categories: Patients with early stage CTCL who have not tolerated other therapies, patients with refractory or persistent early stage CTCL, and patients with refractory advanced stage CTCL; and (2) NDA 20–449/S–011, Taxotere® (docetaxel) for Injection Concentrate, Rhone-Poulenc Rorer Pharmaceuticals, Inc., indicated for the treatment of patients with locally advanced or metastatic Non-small Cell Lung Cancer after failure of prior chemotherapy. On December 14, 1999, the committee will discuss: (1) The design and analysis of active control clinical trials; and (2) NDA 21–156, Celebrex™ (celecoxib), G. D. Searle & Co., indicated for the regression and prevention of adenomatous polyps, which may lead to the development of colorectal cancer in patients with familial adenomatous polyposis.

Procedure: On December 13, 1999, from 9 a.m. to 5:30 p.m., and on December 14, 1999, from 8 a.m. to 3 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 3, 1999. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:30 a.m., and between approximately 1:30 p.m. and 1:45 p.m. on December 13, 1999, and between approximately 10:15 a.m. and 11 a.m. on December 14, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 3, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. After the scientific presentations, a 30-minute open public session will be conducted for interested persons who have submitted their request to speak by December 3, 1999, to address issues specific to the submission or topic before the committee.

Closed Committee Deliberations: On December 14, 1999, from 3 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The investigational new drug application (IND) and Phase I and Phase II drug products in process will be presented, and recent action on selected NDA's will be discussed. This portion of the meeting will be closed to permit discussion of this information.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 2, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–30213 Filed 11-18-99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 14, 1999, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Kimberly L. Topper at Topperk@cder.fda.gov or Angie Whitacre at Whitacrea@cder.fda.gov, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss collaborative approaches to scientific research issues of common interest to the pharmaceutical industry, universities, the public, and FDA. Specific areas of focus will be in the nonclinical studies areas of: (1) Interspecies biomarkers of toxicity, (2) high-resolution magnetic imaging, (3) positron emission tomography imaging, and (4) methods to facilitate early human assessments.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 9, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 9, 1999, and

submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 10, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–30192 Filed 11–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute Proposed Collection; Comment Request The Jackson Heart Study, Full Scale Exam I—Phase III

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: The Jackson Heart Study, Full Scale Exam I—Phase III; Type of Information Collection Request: New. Need and Use of Information Collection: The Jackson Heart Study is a prospective epidemiologic investigation of Cardiovascular Disease (CVD) among African-American adults ages 30 years and older from the Jackson, Mississippi metropolitan area. The examination phase of the study is scheduled to begin in the fall of 2000 and will take approximately three years to complete. An extensive examination is planned and will include a series of questionnaires (dealing with lifestyle habits, medical history, medications, social and cultural factors), physical assessments (height, weight, body size, blood pressure, electrocardiogram, ultrasound measurements of the heart and arteries in the neck, and lung function) and laboratory measurements (cholesterol and other lipids, glucose, indicators related to clotting of the blood, among others). Data collected in this study will include both conventional risk factors and new or emerging factors that may be related to CVD. Some of the newer areas of focus will include early indicators of disease, genetics, socio-cultural influences such as socioeconomic status and discrimination, and physiological relations between common disorders such as high blood pressure, obesity and diabetes and their influence on CVD. The information collected will be used by the public and private sector for public health planning, medical education, other epidemiologic studies, and biomedical research. Frequency of Response: One-time. Affected Public: Individuals or families; Business or other for profit; not-for-profit institutions. Type of Respondents: Adults age 30 years and older, next-of-kin, and physicians.

The annual reporting burden is as follows: Estimated Number of Respondents: 2,567. Estimated Number of Responses per Respondent: 1. Average Burden Hours Per Response are shown in the table below; and Estimated Total Annual Burden Hours Requested: 68,658. The annualized cost to respondents is estimated at: $791,246 consist of their time and assumes a rate of $11.50 per hour for the cohort and next-of-kin decedents and $45 per hour for physicians.

Estimates of the annual reporting burden to respondents.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
JHS individuals of families	2,167	1	31.65	68,575
Morbidity & Mortality AFU next-of-kin decedents	200	1	0.17	33
Morbility & Mortality AFU Physicians	200	1	0.25	50
Total	2,567	.....	.....	68,658

The average annual Capital Costs are $52,800. The average annual Operating and Maintenance Costs are $5,402,000.

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Cheryl Nelson, Jackson Heart Study Project Officer, 6701 Rockledge Drive, Room 8152, MSC 7934, Rockville, MD 20892–7934, or call non-toll-free number (301) 435–0451 or E-mail your request, including your address to: cn80n@.nih.gov

Comments Due Date

Comment regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: November 5, 1999.

Lawrence Friedman,

Director, Division of Epidemiology and Clinical Applications.

[FR Doc. 99–30197 Filed 11–18–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; National Toxicology Program (NTP) Board of Scientific Counselors' Meeting; Review of Nominations for Listing in or Delisting From the 10th Report on Carcinogens

Pursuant to Pub. L. 92–463, notice is hereby given of the next meeting of the NTP Board of Scientific Counselors' Report on Carcinogens (RoC) Subcommittee to be held on January 20 & 21, 2000, at the Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, VA 22202. On January 20, registration will begin at 9 a.m. and the meeting will begin at 9:30 a.m. On January 21, the meeting will begin at 8:30 a.m. Pre-registration is not required; however, persons requesting time to make oral, public comments are asked to notify Dr. Mary S. Wolfe, Executive Secretary, prior to the meeting (contact information given below). The agenda covers the peer review of substances, mixtures, or exposure circumstances nominated for listing in the 10th Report on Carcinogens, and includes an opportunity for public input.

Background

The Department of Health and Human Services (DHHS) Report on Carcinogens (RoC) is a public information document prepared for the US Congress by the National Toxicology Program (NTP) in response to Section 301(b)(4) of the Public Health Service Act, as amended. The intent of the document is to provide a listing of those agents, substances, or exposure circumstances that are either ''known'' or ''reasonably anticipated'' to cause cancer in humans and to which a significant number of people in the United States are exposed. The process for preparation of the RoC has three levels of scientific peer review. Central to the evaluations of the review groups is the use of criteria for inclusion in or removal of substances from the Report. The current criteria for listing in or delisting from the Report were approved by the Secretary, DHHS, in September 1996. The major change in the RoC, which occurred as a result of the criteria revision, was to include consideration of all relevant information, including mechanistic data, in the decision to list in or delist from future editions. The review process for listing in or delisting from the RoC begins with initial scientific review by the National Institute of Environmental Health Sciences (NIEHS)/NTP Report on Carcinogens Review Committee (RG1), which is comprised of NIEHS/NTP staff scientists. The second scientific review group is comprised of representatives from the Federal health research and regulatory agencies that are members of the NTP Executive Committee. Following external public review by the NTP Board RoC Subcommittee and solicitation of public comments through announcements in the **Federal Register** and other media, the independent recommendations of the three scientific peer review groups and all public comments are presented to the NTP Executive Committee for review and comment. All recommendations and public comments are submitted to the Director, NTP, who reviews them and makes a final recommendation to the Secretary, DHHS, concerning the listing or delisting of chemicals or exposure circumstances in the RoC. The Secretary has final review and approval for the Report.

Agenda

The meeting of the NTP RoC Subcommitee is scheduled for January 20 & 21, 2000. Tentatively scheduled to be peer reviewed are nine nominated chemicals or exposure circumstances. These nominations are listed alphabetically in the attached table, along with supporting information and a tentative order of presentation and review. Background summary documents for each of the nominations are available to the public and include (1) A summary of the scientific data and information used to evaluate the nomination, (2) a recommendation for listing either as ''known to be a human carcinogen'' or as ''reasonably anticipated to be a human carcinogen,'' or (3) the upgrading or delisting of a current listing in the RoC. Copies of a draft background summary document for each of these nominations are available on the NTP web homepage at http://ntp-server.niehs.nih.gov/ and the Environmental Health Information Service website at http://ehis.niehs.nih.gov/ or can be obtained in hard copy, as available, from: Dr. C.W. Jameson, Report on Carcinogens, NIEHS, MD EC–14, 79 Alexander Drive, Building 4401, Room 3127, P.O. Box 12233, Research Triangle Park, NC 27709 (919/541–4096; FAX 919/541–2242; email *jameson@niehs.nih.gov*).

The April 2, 1999 **Federal Register** Announcement (Volume 64, Number 63, Page 15983–15984) calling for public comments on the nominations to be reviewed in 1999 for listing in or delisting (removing) from the 10th RoC, indicated that UV Radiation (separate consideration of three segments of the wavelength spectrum: UVA (315–400 nm), UVB (280–315 nm), and UVC (100–280 nm)) and Toluene Diisocyanate (CAS Number 26471–62–5) would be among the nominations to be reviewed. The initial review of the UV Radiation nomination by NTP staff found an extensive published database for this nomination and there was insufficient time to prepare adequately a comprehensive summary background document for its review in 1999. Therefore, the nomination of UV Radiation (separate consideration of three segments of the wavelength spectrum: UVA (315–400 nm), UVB (280–315 nm), and UVC (100–280 nm)) was deferred for review until later in 2000.

Toluene Diisocyanate (TDI) was nominated by the Diisocyanates Panel of the Chemical Manufacturers Association for review and delisting from the RoC. As outlined in the published listing/delisting procedures for the RoC, the RG1 reviewed the nomination and data provided by the Diisocyanates Panel. Based on its review of the available information concerning the carcinogenicity of TDI, the RG1 determined that there is no new, relevant data to support the delisting of TDI from the RoC. RG1 recommended that the nomination to delist TDI from the RoC not proceed any further through the review process. Therefore, TDI is not on the agenda for review at the January 20–21 RoC Subcommittee meeting. The Diisocyanates Panel was notified of this action and invited to resubmit the nomination to delist TDI from the RoC providing additional justification and relevant new data to support the nomination. The RG2, NTP Board of Scientific Counselors RoC Subcommittee, and the NTP Executive Committee were notified of this action.

Solicitation of Public Comment

The NTP Board of Scientific Counselors RoC Subcommittee meeting is open to the public, and time will be provided for public comment on each of the nominations under review. In order to facilitate planning for the meeting, persons requesting time for an oral presentation regarding a particular nomination should notify the Executive Secretary, Dr. Mary S. Wolfe, P.O. Box 12233, A3–07, Research Triangle Park, NC 27709 (telephone 919/541–3971; FAX 919/541–0295; email wolfe@niehs.nih.gov) no later than January 7, 2000. Persons registering to make comments are asked to provide, if possible, a written copy of their statement by January 7th so copies can be made and distributed to

Subcommittee for their timely review prior to the meeting. Written statements can supplement and expand the oral presentation, and each speaker is asked to provide his/her name, affiliation, mailing address, phone, fax, e-mail and supporting organization (if any). At least seven minutes will be allotted to each speaker, and if time permits, can be extended to 10 minutes. Individuals who register to make oral presentations by January 7th will be notified about the time available for their presentation at least one week prior to the meeting. Registration for making public comments will also be available on-site. If registering on-site to speak and reading oral comments from printed copy, the speaker is asked to bring 25 copies of the text. These copies will be distributed to the Chair and Subommittee members and supplement the record.

Written comments, in lieu of making oral comments, are welcome. All comments must include name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization (if any) and should be received by January 7th for distribution to the Subcommittee. Written comments received after January 7th will not be considered by Subcommittee members in their reviews.

The NTP would welcome receiving information from completed, ongoing, or planned human or experimental animal cancer studies, or studies of mechanism of cancer formation, as well as current production data, human exposure information, and use patterns for any of the nominations listed in this announcement. Organizations or individuals that wish to provide information should contact Dr. C.W. Jameson at the address given above.

The agenda and a roster of Subcommittee members will be available prior to the meeting on the NTP web homepage at *http://ntp-server.niehs.nih.gov/* and upon request from Dr. Wolfe. Summary minutes from the previous meeting are available on the NTP web homepage and upon request from Dr. Wolfe.

Dated: November 10, 1999.

Samuel H. Wilson,

Deputy Director, NIEHS and NTP.

SUMMARY DATA FOR NOMINATIONS TENTATIVELY SCHEDULED FOR REVIEW AT THE MEETING OF THE NTP BOARD OF SCIENTIFIC COUNSELORS' REPORT ON CARCINOGENS SUBCOMMITTEE JANUARY 20–21, 2000

Nomination to be reviewed/CAS No.	Primary uses or exposures	To be reviewed for	Tentative review order
Beryllium and Beryllium Compounds/7440–41–7.	Fiber optics and cellular network communications systems, aerospace, defense and other industry applications.	Possible updating of current listing of beryllium and certain beryllium compounds to a known human carcinogen.	3
2,2-bis-(bromomethyl) -1,3-propanediol/3296–90–9.	Used as a fire retardant in unsaturated polyester resins, in molded products, and in rigid polyurethane foam.	Listing in the 10th Report	2
2,3–Dibromo-1–Propanol/96–13–9	Used as a flame retardant, as an intermediate in the preparation of the flame retardant tris(2,3-dibromopropyl) phosphate, and as an intermediate in the manufacture of pesticides and pharmaceutical preparations.	Listing in the 10th Report	1
Dyes Metabolized to Dimethoxybenzidine (Dimethoxybenzidine Dyes as a Class).	Dyes widely used for leather, paper, plastics, rubber, and textile industries.	Listing in the 10th Report	4
Dyes Metabolized to Dimethylbenzidine (Dimethylbenzidine Dyes as a Class).	Dyes widely used for leather, paper, plastics, rubber, and textile industries.	Listing in the 10th Report	5
IQ (2–Amino-3-methylimidazo[4,5-f]quinoline)/76180–96–6.	Found in cooked meat and fish	Listing in the 10th Report	6
Styrene-7,8-oxide/96–09–3	Used mainly in the preparation of fragrances and in some epoxy resin formulations.	Listing in the 10th Report	7
Vinyl Bromide/593–60–2	Used commercially since 1968, primarily in the manufacture of flame retardant synthetic fibers.	Listing in the 10th Report	8
Vinyl Fluoride/75–02–5	Used commercially since the 1960s, in the production of polyvinylfluoride, which is used for plastics.	Listing in the 10th Report	9

[FR Doc. 99–30198 Filed 11–18–99; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Review Phthalates Meeting Notice

National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), Center for the Evaluation of Risks to Human Reproduction, announces the second meeting of an expert panel to review phthalates, December 15–17, 1999. The meeting will be held at Hawthorn Suites Hotel, 300 Meredith Drive, Durham, NC (near the intersection of highways 54 and 55 in Research Triangle Park) and will begin at 8:30 a.m. each day.

Background

The NTP and the NIEHS established the NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) (63 FR 68782, No 239) in June 1998. The purpose of the Center is to provide timely and unbiased, scientifically sound evaluations of human and experimental evidence for adverse effects on reproduction, including development, which may be caused by agents to which humans are exposed. The evaluations produced through the Center will be published as monographs in *Environmental Health Perspectives* (EHP); a special effort will be made to summarize the reports in non-scientific terms for use by the general public. These documents will be available on the CERHR website (http://cerhr.niehs.nih.gov) or in hardcopy by contacting Ms. Peggy Sheren (contact

information given below), and will also be transmitted to appropriate Federal and State Agencies. Public comments on the final documents will be welcome. The Center's first review is underway and covers the evaluation of the following seven phthalate esters (Chemical Abstracts Service registry numbers are in parentheses).

butyl benzyl phthalate (85–68–7)
di(2-ethylhexyl) phthalate (117–81–7)
di-isodecyl phthalate (26761–40–0, 68515–49–1)
di-isononyl phthalate (28553–12–0, 68515–48–0)
di-n-butyl phthalate (84–74–2)
di-n-hexyl phthalate (84–75–3)
di-n-octyl phthalate (117–84–0)

First Meeting of the Expert Panel to Review Phthalates, August 17–19, 1999

An independent, expert panel began the phthalate review at the first Phthalate Expert Panel Meeting on August 17–19 in Alexandria, Virginia (64 FR 42707–42708). Prior to this meeting, panelists reviewed existing literature in their areas of expertise and provided other panel members with their summary evaluations. This effort involved the review of nearly 1,000 reports or publications covering general toxicity in animals and humans, developmental and reproductive toxicity, and information on human exposure. Integrated evaluation documents drafted at the Panel's meeting addressed the nature and consistency of the reviewed data, relevancy of experimental models to humans, and important papers in the areas of toxicity and human exposure.

Draft integrated evaluation documents were reviewed and discussed in plenary session by the Panel for the following phthalates: butyl benzyl phthalate, di(2-ethylhexyl)phthalate, and di-n-octyl phthalate. Further discussion of these draft documents and formulation of summary statements will take place at the second Phthalate Expert Panel Review. A summary of the first Phthalate Expert Panel meeting is available on the Center's website (*http://cerhr.niehs.nih.gov*) or can be obtained in hardcopy from Ms. Sheren (see below).

December 15–17, 1999 Phthalate Expert Panel Review

The integrated evaluations on the four remaining chemicals (di-isodecyl phthalate, di-isononyl phthalate, di-n-butyl phthalate, and di-n-hexyl phthalate) are being written and will be discussed at the Expert Panel meeting to be held December 15–17. The draft integrated evaluations will be publicly available after December 1, 1999 at the Center's website (see above) or can be obtained in hardcopy by contacting Ms. Peggy Sheren, (see below). Following review and agreement by the Panel on the integrated evaluations, the members will develop consensus summary statements for each of the seven phthalates. These narrative statements will reflect a consensus opinion of the Panel as to the developmental and reproductive toxicity of these chemicals in experimental models and will address the potential significance of these results to human reproduction and development. Following this meeting, integrated evaluations and the summary statements will be incorporated into a monograph on phthalates that is published in EHP and available for public comment.

Review Panel and Charge to Panel

A panel of 16 independent scientists selected for their expertise in various aspects of reproductive toxicology and other relevant areas are conducting this review. The roster of experts follows:

Phthalates Expert Panel

Name and Affiliation

Kim Boekelheide, MD, PhD, Brown University, Providence, RI
Bob Chapin, PhD, NIEHS, Research Triangle Park, NC
Mike Cunningham, PhD, NIEHS, Research Triangle Park, NC
Elaine Faustman, PhD, University of Washington, Seattle, WA
Paul Foster, PhD, Chemical Industry Institute of Toxicology, Research Triangle Park, NC
Mari Golub, PhD, Cal/EPA, Davis, CA
Rogene Henderson, PhD, Inhalation Toxicology Research Institute, Albuquerque, NM
Irwin Hinberg, PhD, Health Canada, Ottawa, Ontario, Canada
Bob Kavlock, PhD (chair), EPA/ORD, Research Triangle Park, NC
Ruth Little, Sc.D*, NIEHS, Research Triangle Park, NC
Jennifer Seed, PhD, EPA/OPPT, Washington, DC
Katherine Shea, MD, North Carolina State University, Raleigh, NC
Sonia Tabacova, MD, PhD**, FDA, Rockville, MD
Shelley Tyl, PhD, Research Triangle Institute, Research Triangle Park, NC
Paige Williams, PhD*, Harvard University, Cambridge, MA
Tim Zacharewski, PhD*, Michigan State University, East Lansing, MI

* Unable to attend the second Phthalate Expert Panel meeting.

** Added to the Panel to assist in the evaluation of literature and identification of research and testing needs in epidemiology.

Charge to Expert Panel

Rigorously evaluate all relevant data and reach a conclusion regarding the strength of scientific evidence that exposure to a chemical may or may not present a risk to human reproduction or development.

1. Evaluate all reproductive and developmental toxicity studies—in humans and animals—for quality, completeness, and sufficiency. Determine consistency of reported effects within and among species. Briefly summarize relevant individual studies.

2. Review and summarize related studies paying particular attention to studies of general toxicity, pharmacokinetics, genetic toxicity, and mechanisms of toxicity within and across species. Both *in vivo* and *in vitro* studies will be included.

3. Determine, to the extent possible, patterns of use (such as timing, duration) and exposure (such as dose, route) to humans.

4. Integrate this information, using a weight of evidence approach. Determine how human, animal and other data can reasonably be used to predict reproductive or developmental effects in humans under particular exposure conditions.

5. Provide judgments, including qualitative statements of the certainty of the judgments, that an agent presents a potential risk to human reproduction and/or development. Describe the major factors that contributed to these judgments. State the exposure circumstances under which such risk might be expected to exist.

6. Identify specific areas of uncertainty (such as inadequate pharmacokinetic data in a given species) that would prevent a more definitive assessment of human risk.

7. Identify research and testing needs that, if met, would significantly reduce the uncertainty inherent in the stated judgments of risk.

Meeting Open to the Public

The meeting is open to the public and attendance is limited only by the availability of space. This review will take place from December 15–17 at Hawthorn Suites Hotel, 300 Meredith Drive, Durham, NC (near the intersection of highways 54 and 55 in Research Triangle Park). The meeting commences each day at 8:30 a.m. .

Preliminary Agenda

December 15 (8:30 a.m.)

Opening remarks by Dr. George Lucier, Director, ETP, NIEHS; Dr. Michael Shelby, NIEHS and Director of

the Center; Dr. John Moore, Sciences, International and CERHR; and Dr. Robert Kavlock, EPA and Chair of the Expert Panel on Phthalates.

Following opening remarks, the Panel will receive public comments (time seven minutes per speaker). Information for those wishing to register to give oral comments or to submit written comments is provided below. Following the comment period, draft integrated evaluations for each of the seven phthalates will be discussed in plenary session with the purpose of reaching consensus on each chemical. These draft documents will be available to the public electronically on the CERHR website (*http://cerhr.niehs.nih.gov*) after December 1 or in hardcopy by contacting Ms. Sheren at the address given below.

December 16 (8:30 a.m.)

Complete discussions of the integrated evaluations. Begin drafting summary statements for each of the chemicals. This will be accomplished through an iterative series of workgroup discussions and plenary sessions.

December 17 (8:30 a.m.)

Summary statements reflecting significant conclusions and judgements reached by the Panel Workgroups for each of the phthalates will be presented, discussed, and agreed upon by the entire expert panel in the final plenary session. Closing comments by Dr. Michael Shelby, NIEHS, and Dr. Lynn Goldman, Johns Hopkins University and NIEHS.

Solicitation of Oral and Written Public Comments

Following opening remarks on December 15, time is allotted for public comments (seven minutes per speaker on the chemicals being reviewed). In order to facilitate planning of this meeting, those wishing to make public comments are asked to notify Ms. Sheren, (CERHR, 1800 Diagonal Road, Suite 500, Alexandria, VA 22314–2808, Phone: (703) 838–9440) no later than December 10, 1999. When registering to comment orally, please provide your name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization (if any). If possible, also send a copy of the statement or talking points to Ms. Sheren; this information will be provided to the Panel and will assist the Chair and Panel Members in identifying issues for discussion. Registration for public comments will also be available on-site (7:30–8:30 a.m.). Those registering on site are asked to bring 20 copies of their statement or talking points.

A written statement may be submitted in lieu of making an oral presentation. These written comments should be received by Ms. Sheren (address given above) no later than December 10 in order for them to be considered at the December 15–17 meeting. Persons sending written comments are asked to provide their name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization (if any). .

For other questions or additional information about the meeting, please contact Ms. Sheren.

Dated: November 10, 1999.

Samuel H. Wilson,

Deputy Director, NIEHS and NTP.

[FR Doc. 99–30199 Filed 11–18–99; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4432–N–46]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: November 19, 1999.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, Department of Housing and Urban Development, Room 7262, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: November 10, 1999.

Fred Karnas, Jr.,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 99–29930 Filed 11–18–99; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Klamath Fishery Management Council; Meeting Notice

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. I), this notice announces a meeting of the Klamath Fishery Management Council, established under the authority of the Klamath River Basin Fishery Resources Restoration Act (16 U.S.C. 460ss *et seq.*). The Klamath Fishery Management Council makes recommendations to agencies that regulate harvest of anadromous fish in the Klamath River Basin. The objective of this meeting is to review the progress of the 1999 Klamath chinook salmon fishing season and plan for fishery management in 2000. The meeting is open to the public.

DATES: The Klamath Fishery Management Council will meet from 1:00 p.m. to 5:00 p.m. on Wednesday, December 8, 1999; from 8:00 a.m. to 5:00 p.m. on Thursday, December 9, 1999; and from 8:00 a.m. to 12:00 p.m. on Friday, December 10, 1999.

PLACE: The meeting will be held at the Windmills Inn, 2525 Ashland Street, Ashland, Oregon.

FOR FURTHER INFORMATION CONTACT: Dr. Ronald A. Iverson, Project Leader, U.S. Fish and Wildlife Service, P.O. Box 1006 (1215 South Main), Yreka, California 96097–1006, telephone (530) 842–5763.

SUPPLEMENTARY INFORMATION: For background information on the Klamath Council, please refer to the notice of their initial meeting that appeared in the **Federal Register** on July 8, 1987 (52 FR 25639)

Dated: November 5, 1999.

John Engbring,

Acting Manager, California/Nevada Operations Office.

[FR Doc. 99–30201 Filed 11–18–99; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Geological Survey

Technology Transfer Act of 1986

AGENCY: United States Geological Survey, Interior.

ACTION: Notice of proposed cooperative research and development agreement (CRADA) negotiations.

SUMMARY: The United States Geological Survey (USGS) is contemplating entering into a Cooperative Research and Development Agreement (CRADA) with GeoSIG AG to develop a strong-motion seismograph system.

INQUIRIES: If any other parties are interested in similar activities with the USGS, please contact John R. Evans (650–329–4753 or jrevans@usgs.gov).

SUPPLEMENTARY INFORMATION: This notice is to meet the USGS requirement stipulated in the Survey Manual.

Dated: November 2, 1999.

Steven R. Bohlen,

Acting Chief Geologist.

[FR Doc. 99–30188 Filed 11–18–99; 8:45 am]

BILLING CODE 4310–Y7–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–30–3130–AG; CACA–35742–F1]

AGENCY: Bureau of Land Management, Interior.

ACTION: Opening order, Humboldt, California.

SUMMARY: This notice opens lands to disposal by Recreation and Public Purposes Grant.

EFFECTIVE DATE: Immediately upon publication.

FOR FURTHER INFORMATION CONTACT: Charlotte Hawks, Arcata Field Office, BLM, 1695 Heindon Road, Arcata, CA 95521–4573, (707) 825-2319.

SUPPLEMENTALRY INFORMATION: On November 21, 1995, the land described below was segregated from appropriation under the public land laws and mining laws as part of exchange proposal CACA 35742–F1. The parcel was subsequently dropped from the exchange proposal.

On the date of publication of this notice, the land described below will be opened to the operation of the public land laws, generally, and the mining laws, subject to valid existing rights, other segregations of record, and the requirements of applicable law. The parcel remains segregated from all appropriation by Recreation and Public Purposes Classification CACA 39081.

Humboldt Meridian, California

T.5S., R.3E., Sec. 11, SW1/4SW1/4.

Containing 40.00 acres.

Lynda J. Roush,

Arcata Field Manager.

[FR Doc. 99–30202 Filed 11–18–99; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Proposed Replacement of Wright Water Distribution Looping Project

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Notice of application for grant funding; public comment period on request to fund the Wright Water Distribution Looping Project.

SUMMARY: OSM is announcing its receipt of a grant application from the Wyoming Department of Environmental Quality, Abandoned Mine Land Division (AMLD). Wyoming is requesting $160,000 from the Abandoned Mine Reclamation Fund to pay the cost of replacing the Wright Water Distribution Looping Project. In its application, the State proposes paying for the construction cost as a public facility project that will benefit a community impacted by coal mining.

This notice describes when and where you may read the grant application for funding the Wright Water Distribution Looping Project. It also sets the time period during which you may send written comments on the request to us.

DATES: We will accept written comments until 4:00 p.m., m.s.t., December 20, 1999.

ADDRESSES: You should mail or hand-deliver written comments to Guy V. Padgett, Casper Field Office Director, at the address shown below. You may read Wyoming's grant application for this proposed project during normal business hours Monday through Friday (excluding holidays) at the same address. Also, we will send one free copy of the grant application to you if you contact OSM's Casper Field Office, Guy V. Padgett, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building, Rm. 2403, 100 East ''B'' Street, Casper, Wyoming 82601–1918.

FOR FURTHER INFORMATION CONTACT: Guy V. Padgett, Telephone: (307) 261–6555. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking (or administrative) record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking [or administrative] record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available from public inspection in their entirety.

SUPPLEMENTARY INFORMATION:

I. Background on Title IV of SMCRA

Title IV of the Surface Mining Control and Reclamation Act (SMCRA) established an Abandoned Mine Land Reclamation (AMLR) program. The purpose of the AMLR program is to reclaim and restore lands and waters that were adversely affected by past mining. The program is funded by a reclamation fee paid by active coal mining operations. Lands and waters eligible for reclamation under Title IV are primarily those that were mined, or affected by mining, and abandoned or inadequately reclaimed before August 3, 1977, and for which there is no continuing reclamation responsibility under State, Federal, or other laws.

Title IV of SMCRA allows States to submit AMLR plans to us. We, on behalf of the Secretary, review those plans and consider any public comments we receive about them. If we determine that a State has the ability and necessary legislation to operate an AMLR program, the Secretary can approve it. The Secretary's approval gives a State exclusive authority to put its AMLR plan into effect.

Once the Secretary approves a State's AMLR plan, the State may apply to us for money to fund specific projects that will achieve the goals of its approved plan. We follow the requirements of the Federal regulations at 30 CFR parts 874, 875, and 886 when we review and approve such applications.

II. Background on the Wyoming AMLR Plan

The Secretary of the Interior approved Wyoming's AMLR plan on February 14, 1983. You can find background information on the Wyoming AML program, including the Secretary's findings and our response to comments, in the February 14, 1983 **Federal**

Register (48 FR 6536). Wyoming changed its plan a number of times since the Secretary first approved it. In 1984, we accepted the State's certification that it had addressed all known coal-related impacts in Wyoming that were eligible for funding under its program. As a result, the State may now reclaim low priority non-coal reclamation projects. You can read about the certification and OSM's acceptance in the May 25, 1984, **Federal Register** (49 FR 22139). At the same time, we also accepted Wyoming's proposal that it will ask us for funds to reclaim any additional coal-related problems that occur during the life of the Wyoming AML program as soon as it becomes aware of them. In the April 13, 1992, **Federal Register** (57 FR 12731), we announced our decision to accept other changes in Wyoming's plan that describe how it will rank eligible coal, non-coal, and facility projects for funding. Those changes also authorized the Governor of Wyoming to elevate the priority of a project based upon the Governor's determination of need and urgency. They also expanded the State's ability to construct public facilities under section 411 of SMCRA. We approved additional changes in Wyoming's plan concerning non-coal lien authority and contractor eligibility that improve the efficiency of the State's AML program. That approval is described in the February 21, 1996, **Federal Register** (61 FR 6537).

Once a State certifies that it has addressed all remaining abandoned coal mine problems and the Secretary concurs, then it may request funds to undertake abandoned non-coal mine reclamation, community impact assistance, and public facilities projects under sections 411(b), (e), and (f), of SMCRA.

State law and regulations that apply to the proposed Abandoned Coal Mine Land Program Wright Water Distribution Looping project funding request include Wyoming Statute 35–11–1202 and Wyoming Abandoned Mine Land Regulations, Chapter VII, of the Wyoming Abandoned Mine Program.

III. Wyoming's Request to Fund the Cost of Wright Water Distribution Looping Project

The Wyoming Department of Environmental Quality submitted to us a grant application dated November 1, 1999. In that application, Wyoming asked for $160,000 to pay for the cost of replacing the Wright Water Distribution Project. The Governor of Wyoming certified the need and urgency to fund this project prior to completing the State's remaining inventory of non-coal reclamation work, as allowed by section 411(f) of SMCRA. That certification says the project is in a community impacted by coal mining activities.

This project will mitigate the impacts of safety hazards associated with the present condition of the Wright Water Distribution Looping project. The project will serve the community of Wright by reducing the threat to surface water and public health and safety presented by inadequate water pressure for fire suppression and consumption. The Governor's certification states that safety hazards warrant funding of this project before the remaining inventory of non-coal projects are completed.

IV. How We Will Review Wyoming's Grant Application

We will review this grant application using the regulations at 30 CFR 875.15; specifically subsections 875.15(e)(1) through (7). As stated in those regulations, the application must include the following information: (1) The need or urgency for the activity or the construction of the public facility; (2) the expected impact the project will have on Wyoming's coal or minerals industry; (3) the availability of funding from other sources and, if other funding is provided, its percentage of the total cost involved; (4) documentation from other local, State, and Federal agencies with oversight for such utilities or facilities describing what funding they have available and why their agency is not fully funding this specific project; (5) the impact on the State, the public, and the minerals industry if the facility is not funded; (6) the reasons why this project should be selected before the priority project relating to the protection of the public health and safety or the environment from the damages caused by past mining activities, and (7) an analysis and review of the procedures Wyoming used to notify and involve the public in this request, and a copy of all comments received and their resolution by the State. Wyoming's application for the Wright project contains the information described in these seven subsections.

Section 875.15(f) requires us to evaluate all comments we receive and determine whether the funding meets the requirements of §§ 875.15(e)(1) through (7) described above. It also requires us to determine if the request is in the best interests of the State's AML program. We will approve Wyoming's request to fund this project if we conclude that it meets all the requirements of 30 CFR 875.15.

V. What To Do if You Want To Comment on the Proposed Project

We are asking for public comments on Wyoming's request for funds to pay for the cost of replacing the Wright Water Distribution Looping project. You are welcome to comment on the project. If you do, please send us written comments. Make sure your comments are specific and pertain to Wyoming's funding request in the context of the regulations at 30 CFR 875.15 and the provisions of section 411 of SMCRA. You should explain any recommendations you make. If we receive your comments after the time shown under **DATES** or at locations other than the Casper Field Office, we will not necessarily consider them in our final decision or include them in the administrative record.

Dated: November 3, 1999.

Guy Padgett,

Director, Casper Field Office.

[FR Doc. 99–30255 Filed 11–18–99; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Proposed Replacement of Riverton Sewage Treatment Plant Pump

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Notice of application for grant funding; public comment period on request to fund the Riverton Sewage Treatment Plant Pump replacement.

SUMMARY: OSM is announcing its receipt of a grant application from the Wyoming Department of Environmental Quality, Abandoned Mine Land Division (AMLD). Wyoming is requesting $160,000 from the Abandoned Mine Reclamation Fund to pay the cost of replacing the Riverton Sewage Treatment Plan Pump. In its application, the State proposes paying for the construction cost as a public facility project that will benefit a community impacted by iron and uranium mining.

This notice describes when and where you may read the grant application for funding the Riverton Sewage Treatment Plant Pump project. It also sets the time period during which you may send written comments on the request to us.

DATES: We will accept written comments until 4:00 p.m., m.s.t., December 20, 1999.

ADDRESSES: You should mail or hand-deliver written comments to Guy V. Padgett, Casper Field Office Director, at the address shown below. You may read Wyoming's grant application for this proposed project during normal business hours Monday through Friday (excluding holidays) at the same address. Also, we will send one free copy of the grant application to you if you contact OSM's Casper Field Office.

Guy V. Padgett, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building, Rm. 2403, 100 East ''B'' Street, Casper, Wyoming 82601–1918.

FOR FURTHER INFORMATION CONTACT: Guy V. Padgett, Telephone: (307) 261–6555.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking (or administrative) record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking (or administrative) record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

SUPPLEMENTARY INFORMATION:

I. Background on Title IV of SMCRA

Title IV of the Surface Mining Control and Reclamation Act (SMCRA) established an Abandoned Mine Land Reclamation (AMLR) program. The purpose of the AMLR program is to reclaim and restore lands and waters that were adversely affected by past mining. The program is funded by a reclamation fee paid by active coal mining operations. Lands and waters eligible for reclamation under Title IV are primarily those that were mined, or affected by mining, and abandoned or inadequately reclaimed before August 3, 1977, and for which there is no continuing reclamation responsibility under State, Federal, or other laws.

Title IV of SMCRA allows States to submit AMLR plans to us. We, on behalf of the Secretary, review those plans and consider any public comments we receive about them. If we determine that a State has the ability and necessary legislation to operate an AMLR program, the Secretary can approve it. The Secretary's approval gives a State exclusive authority to put its AMLR plan into effect.

Once the Secretary approves a State's AMLR plan, the State may apply to us for money to fund specific projects that will achieve the goals of its approved plan. We follow the requirements of the Federal regulations at 30 CFR parts 874, 875, and 886 when we review and approve such applications.

II. Background on the Wyoming AMLR Plan

The Secretary of the Interior approved Wyoming's AMLR plan on February 15, 1983. You can find background information on the Wyoming AML program, including the Secretary's findings and our responses to comments, in the February 14, 1983 **Federal Register** (48 FR 6536). Wyoming changed its plan a number of times since the Secretary first approved it. In 1984, we accepted the State's certification that it had addressed all known coal-related impacts in Wyoming that were eligible for funding under its program. As a result, the State may now reclaim low priority non-coal reclamation projects. You can read about the certification and OSM's acceptance in the May 25, 1984, **Federal Register** (49 FR 22139). At the same time, we also accepted Wyoming's proposal that it will ask us for funds to reclaim any additional coal-related problems that occur during the life of the Wyoming AML program as soon as soon as it becomes aware of them. In the April 13, 1992, **Federal Register** (57 FR 12731), we announced our decision to accept other changes in Wyoming's plan that describe how it will rank eligible coal, non-coal, and facility projects for funding. Those changes also authorized the Governor of Wyoming to elevate the priority of a project based upon the Governor's determination of need and urgency. They also expanded the State's ability to construct public facilities under section 411 of SMCRA. We approved additional changes in Wyoming's plan concerning non-coal lien authority and contractor eligibility that improve the efficiency of the State's AML program. That is described in the February 21, 1996, **Federal Register** (61 FR 6537).

Once a State certifies that it has addressed all remaining abandoned coal mine problems and the Secretary concurs, then it may request funds to undertake abandoned non-coal mine reclamation, community impact assistance, and public facilities projects under sections 411(b), (e), and (f), of SMCRA.

State law regulations that apply to the proposed Abandoned Coal Mine Land Program Riverton Sewage Treatment Plant Pump replacement project funding request include Wyoming Statute 35–11–1202 and Wyoming Abandoned Mine Land Regulations, Chapter VII, of the Wyoming Abandoned Mine Program.

III. Wyoming's Request To Fund the Cost of Riverton Sewage Treatment Plant Pump Project

The Wyoming Department of Environmental Quality submitted to us a grant application dated November 1, 1999. In the application, Wyoming asked for $160,000 to pay for the cost of replacing the Riverton Sewage Treatment Plant Pump. The Governor of Wyoming certified the need and urgency to fund this project prior to completing the State's remaining inventory of non-coal reclamation work, as allowed by section 411(f) of SMCRA. That certification says the project is in a community impacted by uranium and iron mining activities.

This project will mitigate the impacts of safety hazards associated with the present condition of the Riverton Sewage Treatment Plant Pumps. The project will serve the community of Riverton by reducing the threat to surface water and public health and safety presented by untreated sewage. The Governor's certification states that safety hazards warrant funding of this project before the remaining inventory of non-coal projects are completed.

IV. How We Will Review Wyoming's Grant Application

We will review this grant application using the regulations at 30 CFR 875.15; specifically § 875.15(e)(1) through (7). As stated in those regulations, the application must include the following information: (1) The need or urgency for the activity or the construction of the public facility; (2) the expected impact the project will have on Wyoming's coal or minerals industry; (3) the availability of funding from other sources and, if other funding is provided, its percentage of the total cost involved; (4) documentation from the local, State, and Federal agencies with oversight for such utilities or facilities describing what funding they have available and why their agency is not fulling funding this specific project; (5) the impact on the State, the public, and the minerals industry if the facility is not funded; (6) the reason why this project should be selected before the priority project relating to the protection of the public

health and safety or the environment from the damages cause by past mining activities, and (7) an analysis and review of the procedures Wyoming used to notify and involve the public in this request, and a copy of all comments received and their resolution by the State. Wyoming's application for the Riverton project contains the information described in these seven subsections.

Section 875.15(f) requires us to evaluate all comments we receive and determine whether the funding meets the requirements of § 875.15(e)(1) through (7) described above. It also requires us to determine if the request is in the best interests of the State's AML program. We will approve Wyoming's request to fund this project if we conclude that it meet all the requirements of 30 CFR 875.15.

V. What To Do if You Want to Comment on the Proposed Project

We are asking for public comments on Wyoming's request for funds to pay for the cost of replacing the Riverton Sewage Treatment Plant pump. You are welcome to comment on the project. If you do, please send us written comments. Make sure your comments are specific and pertain to Wyoming's funding request in the context of the regulations at 30 CFR 875.15 and the provisions of section 411 of SMSRA. You should explain any recommendations you make. If we receive your comments after the time shown under **DATES** or at locations or at locations other than the we receive your comments after the time shown under **DATES** or at locations other than the Casper Field Office, we will not necessarily consider them in our final decision or include them in the administrative record.

Dated: November 3, 1999.

Guy Padget,

Director, Casper Field Office.

[FR Doc. 99–30256 Filed 11–18–99; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Proposed Construction of Lander Water Treatment System

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Notice of application for grant funding; public comment period on request to fund the Lander Water Treatment System.

SUMMARY: OSM is announcing its receipt of a grant application from the Wyoming Department of Environmental Quality, Abandoned Mine Land Division (AMLD). Wyoming is requesting $887,239 from the Abandoned Mine Reclamation Fund to pay for the cost of building the Lander Water Treatment System. In its application, the State proposes paying for part of the reconstruction cost as a public facility project that will benefit a community impacted by iron and uranium mining.

This notice describes when and where you may read the grant application for funding the Lander Water Treatment System project. It also sets the time period during which you may send written comments on the request to us.

DATES: We will accept written comments until 4:00 p.m., m.s.t., December 20, 1999.

ADDRESSES: You should mail or hand-deliver written comments to Guy V. Padgett, Casper Field Office Director, at the address shown below. You may read Wyoming's grant application for this proposed project during normal business hours Monday through Friday (excluding holidays) at the same address. Also, we will send one free copy of the grant application to you if you contact OSM's Casper Field Office.

Guy V. Padgett, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building, Rm. 2403, 100 East ''B'' Street, Casper, Wyoming 82601–1918.

FOR FURTHER INFORMATION CONTACT: Guy V. Padgett, Telephone: (307) 261–6555. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking (or administrative) record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking [or administrative] record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

SUPPLEMENTARY INFORMATION:

I. Background on Title IV of SMCRA

Title IV of the Surface Mining Control and Reclamation Act (SMCRA) established an Abandoned Mine Land Reclamation (AMLR) program. The purpose of the AMLR program is to reclaim and restore lands and waters that were adversely affected by past mining. The program is funded by a reclamation fee paid by active coal mining operations. Lands and waters eligible for reclamation under Title IV are primarily those that were mined, or affected by mining, and abandoned or inadequately reclaimed before August 3, 1977, and for which there is no continuing reclamation responsibility under State, Federal, or other laws.

Title IV of SMCRA allows States to submit AMLR plans to us. We, on behalf of the Secretary, review those plans and consider any public comments we receive about them. If we determine that a State has the ability and necessary legislation to operate an AMLR program, the Secretary can approve it. The Secretary's approval gives a State exclusive authority to put its AMLR plan into effect.

Once the Secretary approves a State's AMLR plan, the State may apply to us for money to fund specific projects that will achieve the goals of its approved plan. We follow the requirements of the Federal regulations at 30 CFR parts 874, 875, and 886 when we review and approve such applications.

II. Background on the Wyoming AMLR Plan

The Secretary of the Interior approved Wyoming's AMLR plan on February 14, 1983. You can find background information on the Wyoming AML program, including the Secretary's findings and our responses to comments, in the February 14, 1983 **Federal Register** (48 FR 6536). Wyoming changed its plan a number of times since the Secretary first approved it. In 1984, we accepted the State's certification that it had addressed all known coal-related impacts in Wyoming that were eligible for funding under its program. As a result, the State may now reclaim low priority non-coal reclamation projects. You can read about the certification and OSM's acceptance in the May 25, 1984, **Federal Register** (49 FR 22139). At the same time, we also accepted Wyoming's proposal that it will ask us for funds to reclaim any additional coal related problems that occur during the life of the Wyoming AML program as soon as it becomes aware of them. In the April 13, 1992, **Federal Register** (57 FR 12731), we announced our decision to

accept other changes in Wyoming's plan that describe how it will rank eligible coal, non-coal, and facility projects for funding. Those changes also authorized the Governor of Wyoming to elevate the priority of a project based upon the Governor's determination of need and urgency. They also expanded the State's ability to construct public facilities under section 411 of SMCRA. We approved additional changes in Wyoming's plan concerning non-coal lien authority and contractor eligibility that improve the efficiency of the State's AML program. That approval is described in the February 21, 1996, **Federal Register** (61 FR 6537).

Once a State certifies that it has addressed all remaining abandoned coal mine problems and the Secretary concurs, then it may request funds to undertake abandoned non-coal mine reclamation, community impact assistance, and public facilities projects under sections 411(b), (e), and (f), of SMCRA.

State law and regulations that apply to the proposed Abandoned Coal Mine Land Program Lander Water Treatment System funding request include Wyoming Statute 35–11–1202 and Wyoming Abandoned Mine Land Regulations, Chapter VII, of the Wyoming Abandoned Mine Program.

III. Wyoming's Request To Fund the Cost of Lander Water Treatment System

The Wyoming Department of Environmental Quality submitted to us a grant application dated November 1, 1999. In that application, Wyoming asked for $887,239 to pay for the cost of constructing the Lander Water Treatment System. The Governor of Wyoming certified the need and urgency to fund this project prior to completing the State's remaining inventory of non-coal reclamation work, as allowed by section 411(f) of SMCRA. That certification says the project is in a community impacted by iron and uranium mining activities. The facility consists of total replacement of the water treatment system in the community of Lander, Wyoming. This project will mitigate the impacts of safety hazards associated with the present condition of the Lander Water System. This project will serve the City of Lander by reducing the drinking water borne threat to the public health and safety presented by giardia, crypto and fecal coliform. The Governor's certification states that safety hazards warrant funding of this project before the remaining inventory of non-coal projects are completed.

IV. How We Will Review Wyoming's Grant Application

We will review this grant application using the regulations at 30 CFR 875.15; specifically § 875.15(e) (1) through (7). As stated in those regulations, the application must include the following information: (1) The need or urgency for the activity or the construction of the public facility; (2) the expected impact the project will have on Wyoming's coal or minerals industry; (3) the availability of funding from other sources and, if other funding is provided, is percentage of the total cost involved; (4) documentation from other local, State, and Federal agencies with oversight for such utilities or facilities describing what funding they have available and why their agency is not fulling funding this specific project; (5) the impact on the State, the public, and the minerals industry if the facility is not funded; (6) the reason why this project should be selected before the priority project relating to the protection of the public health and safety or the environment from the damages cause by past mining activities, and (7) an analysis and review of the procedures Wyoming used to notify and involve the public in this request, and a copy of all comments received and their resolution by the State. Wyoming's application for the Lander Water Treatment System project contains the information described in these seven subsections.

Section 875.15(f) requires us to evaluate all comments we receive and determine whether the funding meets the requirements of §§ 875.15(e) (1) through (7) described above. It also requires us to determine if the request is in the best interests of the State's AML program. We will approve Wyoming's request to fund this project if we conclude that it meets all the requirements of 30 CFR 875.15.

V. What To Do if You Want to Comment on the Proposed Project

We are asking for public comments on Wyoming's request for funds to pay for part of the cost of reconstructing the Lander water system. You are welcome to comment on the project. If you do, please send us written comments. Make sure your comments are specific and pertain to Wyoming's funding request in the context of the regulations at 30 CFR 875.15 and the provisions of section 411 of SMCRA. You should explain any recommendations you make. If we receive your comments after the time shown under **DATES** or at locations other than the Casper Field Office, we will not necessarily consider them in our final decision or include them in the administrative record.

Dated: November 3, 1999.

Guy Padgett,

Director, Casper Field Office.

[FR Doc. 99–30257 Filed 11–18–99; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Proposed Construction of Frannie Water Distribution System

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Notice of application for grant funding; public comment period on request to fund the Frannie Water Distribution System.

SUMMARY: OSM is announcing its receipt of a grant application from the Wyoming Department of Environmental Quality, Abandoned Mine Land Division (AMLD). Wyoming requesting $420,200 from the Abandoned Mine Reclamation fund to pay approximately 44 percent of the cost of building the Frannie Water Distribution System. The Frannie community will provide $37,500. The Rural Utility Service will provide $464,000. The State Loan and Investment Board will provide $29,300. In its application, the State proposes paying for part of the reconstruction cost as a public facility project that will benefit a community impacted by bentonite and gypsum mining.

This notice describes when and where you may read the grant application for funding the Frannie Water Distribution System project. It also sets the time period during which you may send written comments on the request to us.

DATES: We will accept comments until 4:00 p.m., m.s.t., December 20, 1999.

ADDRESSES: You should mail or hand-deliver written comments to Guy V. Padgett, Casper Field Office Director, at the address shown below. You may read Wyoming's grant application for this proposed project during normal business hours Monday through Friday (excluding holidays) at the same address. Also, we will send one free copy of the grant application to you if you contact OSM's Casper Field Office. Guy V. Padgett, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building, Rm. 2403, 100 East ''B'' Street, Casper, Wyoming 82601–1918.

FOR FURTHER INFORMATION CONTACT: Guy V. Padgett, Telephone: (307) 261–6555.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking (or administrative) record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking (or administrative) record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

SUPPLEMENTARY INFORMATION:

I. Background on Title IV of SMCRA

Title IV of the Surface Mining Control and Reclamation Act (SMCRA) established an Abandoned Mine Land Reclamation (AMLR) program. The purpose of the AMLR program is to reclaim and restore lands and waters that were adversely affected by past mining. The program is funded by a reclamation fee paid by active coal mining operations. Lands and waters eligible for reclamation under Title IV are primarily those that were mined, or affected by mining, and abandoned or inadequately reclaimed before August 3, 1977, and for which there is no continuing reclamation responsibility under State, Federal, or other laws.

Title IV of SMCRA allows States to submit AMLR plans to us. We, on behalf of the Secretary, review those plans and consider any public comments we receive about them. If we determine that a state has the ability and necessary legislation to operate an AMLR program, the Secretary can approve it. The Secretary's approval gives a State exclusive authority to put its AMLR plan into effect.

Once the Secretary approves a State's AMLR plan, the State may apply to us for money to fund specific projects that will achieve the goals of its approved plan. We follow the requirements of the Federal regulations at 30 CFR parts 874, 875, and 886 when we review and approve such applications.

II. Background on the Wyoming AMLR Plan

The Secretary of the Interior approved Wyoming's AMLR plan on February 14, 1983. You can find background information on the Wyoming AML program, including the Secretary's findings and our responses to comments, in the February 14, 1983 **Federal Register** (48 FR 6536). Wyoming changed its plan a number of times since the Secretary first approved it. In 1984, we accepted the State's certification that it had addressed all known coal-related impacts in Wyoming that were eligible for funding under its program. As a result, the State may now reclaim low priority non-coal reclamation projects. You can read about the certification and OSM's acceptance in the May 25, 1984, **Federal Register** (49 FR 22139). At the same time, we also accepted Wyoming's proposal that it will ask us for funds to reclaim any additional coal-related problems that occur during the life of the Wyoming AML program as soon as it becomes aware of them. In the April 13, 1992, **Federal Register** (57 FR 12731), we announced our decision to accept other changes in Wyoming's plan that describe how it will rank eligible coal, non-coal, and facility projects for funding. Those changes also authorized the Governor of Wyoming to elevate the priority of a project based upon the Governor's determination of need and urgency. They also expanded the State's ability to construct public facilities under section 411 of SMCRA. We approved additional changes in Wyoming's plan concerning non-coal lien authority and contractor eligibility that improve the efficiency of the State's AML program. That approval is described in the February 21, 1996, **Federal Register** (61 FR 6537).

Once a State certifies that it has addressed all remaining abandoned coal mine problems and the Secretary concurs, then it may request funds to undertake abandoned non-coal mine reclamation, community impact assistance, and public facilities projects under sections 411(b), (e), and (f), of SMCRA.

State law and regulations that apply to the proposed Abandoned Coal Mine Land Program Frannie Water Distribution System funding request include Wyoming Statute 35–11–1202 and Wyoming Abandoned Mine Land Regulations, Chapter VII, of the Wyoming Abandoned Mine Program.

III. Wyoming's Request to Fund the Cost of Frannie Water Distribution System

The Wyoming Department of Environmental Quality submitted to us a grant application dated November 1, 1999. In that application, Wyoming asked for $420,200 to pay for a part of the cost of constructing the Frannie Water Distribution System. The Governor of Wyoming certified the need and urgency to fund this project prior to completing the State's remaining inventory of noncoal reclamation work, as allowed by section 411(f) of SMCRA. That certification says the project is in a community impacted by bentonite and gypsum mining activities. The facility consists of total replacement of the water distribution system in the community of Frannie, Wyoming.

This project will mitigate the impacts of safety hazards associated with the present condition of the Frannie Water System. The Frannie water system is inadequate for fire suppression. The Governor's certification states that safety hazards warrant funding of this project before the remaining inventory of non-coal projects and completed.

IV. How We Will Review Wyoming's Grant Applicant

We will review this grant application using the regulations at 30 CFR 875.15; specifically §§ 875.15(e)(1) through (7). As stated in those regulations, the application must include the following information: (1) The need or urgency for the activity or the construction of the public facility; (2) the expected impact the project will have on Wyoming's coal or minerals industry; (3) the availability of funding from other sources and, if other funding is provided, its percentage of the total cost involved; (4) documentation from other local, State, and Federal agencies with oversight for such utilities or facilities describing what funding they have available and why their agency is not fully funding this specific project; (5) the impact on the State, the public, and the minerals industry if the facility is not funded; (6) the reason why this project should be selected before the priority project relating to the protection of the public health and safety or the environment from the damages cause by past mining activities, and (7) and analysis and review of the procedures Wyoming used to notify and involve the public in this request, and a copy of all comments received and their resolution by the State. Wyoming's application for the Frannie Water Distribution System project contains the information described in these seven subsections.

Section 875.15(f) requires us to evaluate all comments we receive and determine whether the funding meets the requirements of §§ 875.15(e)(1) through (7) described above. It also requires us to determine if the request is in the best interests of the State's AML program. We will approve Wyoming's request to fund this project

if we conclude that it meets all the requirements of 30 CFR 875.15.

V. What to Do if You Want to Comment on the Proposed Project

We are asking for public comments on Wyoming's request for funds to pay for part of the cost of reconstructing the Frannie water system. You are welcome to comment on the project. If you Wyoming's funding request in the context of the regulations at 30 CFR 875.15 and the provisions of section 411 of SMCRA. You should explain any recommendations you make. If we receive your comments after the time shown under DATES or at locations other than the Casper Field Office, we will not necessarily consider them in our final decision or include them in the administrative record.

Dated: November 3, 1999.

Guy Padgett,

Director, Casper Field Office.

[FR Doc. 99–30258 Filed 11–18–99; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Proposed Construction of Etna Water Distribution System

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Notice of application for grant funding, public comment period on request to fund the Etna Water Distribution System.

SUMMARY: OSM is announcing its receipt of a grant application from the Wyoming Department of Environmental Quality, Abandoned Mine Land Division (AMLD). Wyoming is requesting $111,500.00 from the Abandoned Mine Reclamation Fund to pay approximately 8 percent of the cost of building the Etna Water Distribution System. The Wyoming Water Development Commission will provide $689,300. The Rural Utility Service will provide $540,000. In its application, the State proposes paying for part of the reconstruction cost as a public facility project that will benefit a community impacted by coal and mineral mining.

This notice describes when and where you may read the grant application for funding the Etna Water Distribution System project. It also sets the time period during which you may send written comments on the request to us.

DATES; We will accept written comments until 4:00 p.m., m.s.t., December 20, 1999.

ADDRESSES; You should mail or hand-deliver written comments to Guy V. Padgett, Casper Field Office Director, at the address shown below. You may read Wyoming's grant application for this proposed project during normal business hours Monday through Friday (excluding holidays) at the same address. Also, we will send one free copy of the grant application to you if you contact OSM's Casper Field Office. Guy V. Padgett, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building, Rm. 2403, 100 East ''B'' Street, Casper, Wyoming 82601–1918.

FOR FURTHER INFORMATION CONTACT: Guy V. Padgett, Telephone: (307) 261–6555.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking (of administrative) record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking [or administrative] record a respondent's identity, as allowable by law. If you wish us to withhold your name/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions form organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

SUPPLEMENTARY INFORMATION:

I. Background on Title IV of SMCRA

Title IV of the Surface Mining Control and Reclamation Act (SMCRA) established an Abandoned Mine Land Reclamation (AMLR) program. The purpose of the AMLR program is to reclaim and restore lands and waters that were adversely affected by past mining. The program is funded by a reclamation fee paid by active coal mining operations. Lands and waters eligible for reclamation under Title IV are primarily those that were mined, or affected by mining, and abandoned or inadequately reclaimed before August 3, 1977, and for which there is no continuing reclamation responsibility under State, Federal, or other laws.

Title IV of SMCRA allows States to submit AMLR plans to us. We, on behalf of the Secretary, review those plans and consider any public comments we receive about them. If we determine that a State has the ability and necessary legislation to operate an AMLR program, the Secretary can approve it. The Secretary's approval gives a State exclusive authority to put its AMLR plan into effect.

Once the Secretary approves a State's AMLR plan, the State may apply to us for money to fund specific projects that will achieve the goals of its approved plan. We follow the requirements of the Federal regulations at 30 CFR Parts 874, 875, and 886 when we review and approve such applications.

II. Background on the Wyoming AMLR Plan

The Secretary of the Interior approved Wyoming's AMLR plan on February 14, 1983. You can find background information on the Wyoming AML program, including the Secretary's findings and our responses to comments, in the February 14, 1983 **Federal Register** (48 FR 6536). Wyoming changed its plan a number of times since the Secretary first approved it. In 1984, we accepted the State's certification that it had addressed all known coal-related impacts in Wyoming that were eligible for funding under its program. As a result, the State may now reclaim low priority non-coal reclamation projects. You can read about the certification and OSM's acceptance in the May 25, 1984, **Federal Register** (49 FR 22139). At the same time, we also accepted Wyoming's proposal that it will ask us for funds to reclaim any additional coal-related problems that occur during the life of the Wyoming AML program as soon as it becomes aware of them. In the April 13, 1992, **Federal Register** (57 FR 12731), we announced our decision to accept other changes in Wyoming's plan that describe how it will rank eligible coal, non-coal, and facility projects for funding. Those changes also authorized the Governor of Wyoming to elevate the priority of a project based upon the Governor's determination of need and urgency. They also expanded the State's ability to construct public facilities under section 411 of SMCRA. We approved additional changes in Wyoming's plan concerning non-coal lien authority and contractor eligibility that improve the efficiency of the State's AML program. That approval is described in the February 21, 1996, **Federal Register** (61 FR 6537).

Once a State certifies that it has addressed all remaining abandoned coal mine problems and the Secretary concurs, then it may request funds to undertake abandoned non-coal mine

reclamation, community impact assistance, and public facilities projects under sections 411 (b), (e), and (f), of SMCRA.

State law and regulations that apply to the proposed Abandoned Coal Mine Land Program Etna Water Distribution System funding request include Wyoming Statute 35–11–1202 and Wyoming Abandoned Mine Land Regulations, Chapter VII, of the Wyoming Abandoned Mine Program.

III. Wyoming's Request To Fund the Cost of Etna Water Distribution System

The Wyoming Department of Environmental Quality submitted to us a grant application dated November 1, 1999. In that application, Wyoming asked for $111,500 to pay for a part of the cost of constructing the Etna Water Distribution System. The Governor of Wyoming certified the need and urgency to fund this project prior to completing the State's remaining inventory of non-coal reclamation work, as allowed by section 411(f) of SMCRA. That certification says the project is in a community impacted by coal mining activities. The requested funding is approximately 8 percent of the project's total cost. Money for the balance of the project cost will come from the Wyoming Water Development Commission ($689,300) and the Rural Utility Service ($540,000). The facility consists of storage, transmission, and distribution upgrades to the water distribution system in the community of Etna, Wyoming.

This project will mitigate the impacts of safety hazards associated with the present condition of the Etna Water System. The Etna water system is experiencing serious bacteriological risks as demonstrated by an EPA Administrative Order. The Governor's certification states that safety hazards warrant funding of this project before the remaining inventory of non-coal projects are completed.

IV. How We Will Review Wyoming's Grant Application

We will review this grant application using the regulations at 30 CFR 875.15; specifically § 875.15(e)(1) through (7). As stated in those regulations, the application must include the following information: (1) The need or urgency for the activity or the construction of the public facility; (2) the expected impact the project will have on Wyoming's coal or minerals industry; (3) the availability of funding from other sources and, if other funding is provided, its percentage of the total cost involved; (4) documentation from other local, State, and Federal agencies with oversight for such utilities or facilities describing what funding they have available and why their agency is not fully funding this specific project; (5) the impact on the State, the public, and the minerals industry if the facility is not funded; (6) the reason why this project should be selected before the priority project relating to the protection of the public health and safety or the environment from the damages caused by past mining activities, and (7) an analysis and review of the procedures Wyoming used to notify and involve the public in this request, and a copy of all comments received and their resolution by the State. Wyoming's application for the Etna Water Distribution System project contains the information described in these seven subsections.

Section 875.15(f) requires us to evaluate all comments we receive and determine whether the funding meets the requirements of § 875.15(e)(1) through (7) described above. It also requires us to determine if the request is in the best interests of the State's AML program. We will approve Wyoming's request to fund this project if we conclude that it meets all the requirements of 30 CFR 875.15.

V. What To Do if You Want To Comment on the Proposed Project

We are asking for public comments on Wyoming's request for funds to pay for part of the cost of reconstructing the Etna water system. You are welcome to comment on the project. If you do, please send us written comments. Make sure your comments are specific and pertain to Wyoming's funding request in the context of the regulations at 30 CFR 875.15 and the provisions of section 411 of SMCRA. You should explain any recommendations you make. If we receive your comments after the time shown under **DATES** or at locations other than the Casper Field Office, we will not necessarily consider them in our final decision or include them in the administrative record.

Dated: November 3, 1999.

Guy Padgett,

Director, Casper Field Office.

[FR Doc. 99–30259 Filed 11–18–99; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Proposed Construction of Converse County Road 37

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Notice of application for grant funding; public comment period on request to fund the Converse County Road 37.

SUMMARY: OSM is announcing its receipt of a grant application from the Wyoming Department of Environmental Quality, Abandoned Mine Land Division (AMLD). Wyoming is requesting $246,500.00 from the Abandoned Mine Reclamation Fund to pay 50 percent of the cost of building Converse County Road 37 in Converse County, Wyoming. The Power River Coal Company will provide $71,750. Kennocott Energy Company will provide $71,750 and Converse County will provide $103,000. In its application, the State purposes paying for part of the reconstruction cost as a public facility project that will benefit a community impacted by coal and mineral mining.

This notice describes when and where you may read the grant application for funding the Converse County Road 37 project. It also sets the time period during which you may send written comments on the request to us.

DATES: We will accept written comments until 4:00 p.m., m.s.t., December 20, 1999.

ADDRESSES: You should mail or hand-deliver written comment to Guy V. Padgett, Casper Field Office Director, at the address shown below. You may read Wyoming's grant application for this proposed project during normal business hours Monday through Friday (excluding holidays) at the same address. Also, we will send one free copy of the grant application to you if you contact OSM's Casper Field Office. Guy V. Padgett, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building, Rm. 2403, 100 East ''B'' Street, Caster, Wyoming 82601–1918.

FOR FURTHER INFORMATION CONTACT: Guy V. Padgett, Telephone (307) 261–6555.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking [or administrative] record, which we will honor to the

extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking [or administrative] record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

SUPPLEMENTARY INFORMATION:

I. Background on Title IV of SMCRA

Title IV of the Surface Mining Control and Reclamation Act (SMCRA) established an Abandoned Mine Land Reclamation (AMLR) program. The purpose of the AMLR program is to reclaim and restore lands and waters that were adversely affected by past mining. The program is funded by a reclamation fee paid by active coal mining operations. Lands and waters eligible for reclamation under Title IV are primarily those that were mined, or affected by mining, and abandoned or inadequately reclaimed before August 3, 1977, and for which there is no continuing reclamation responsibility under State, Federal, or other laws.

Title IV of SMCRA allows States to submit AMLR plans to us. We, on behalf of the Secretary, review those plans and consider any public comments we receive about them. If we determine that a State has the ability and necessary legislation to operate an AMLR program, the Secretary can approve it. The Secretary's approval gives a State exclusive authority to put its AMLR plan into effect.

Once the Secretary approves a State's AMLR plan, the State may apply to us for money to fund specific projects that will achieve the goals of its approved plan. We follow the requirements of the Federal regulations at 30 CFR parts 874, 875, and 886 when we review and approve such applications.

II. Background on the Wyoming AMLR Plan

The Secretary of the Interior approved Wyoming's AMLR plan on February 14, 1983. You can find background information on the Wyoming AML program, including the Secretary's findings and our responses to comments, in the February 14, 1983 **Federal Register** (48 FR 6536). Wyoming changed its plan a number of times since the Secretary first approved it. In 1984, we accepted the State's certification that it had addressed all known coal-related impacts in Wyoming that were eligible for funding under its program. As a result, the State may now reclaim low priority non-coal reclamation projects. You can read about the certification and OSM acceptance in the May 25, 1984, **Federal Register** (49 FR 22139). At the same time, we also accepted Wyoming's proposal that it will ask us for funds to reclaim any additional coal-related problems that occur during the life of the Wyoming AML program as soon as it becomes aware of them. In the April 13, 1992, **Federal Register** (57 FR 12731), we announced our decision to accept other changes in Wyoming's plan that describe how it will rank eligible coal, non-coal, and facility projects for funding. Those changes also authorized the Governor of Wyoming to elevate the priority of a project based upon the Governor's determination of need and urgency. They also expanded the State's ability to construct public facilities under section 411 of SMCRA. We approved additional changes in Wyoming's plan concerning non-coal lien authority and contractor eligibility that improve the efficiency of the State's AML program. That approval is described in the February 21, 1996, **Federal Register** (61 FR 6537).

Once a State certifies that it has addressed all remaining abandoned coal mine problems and the Secretary concurs, then it may request funds to undertake abandoned non-coal mine reclamation, community impact assistance, and public facilities projects under sections 411(b), (e), and (f), of SMCRA.

State law and regulations that apply to the proposed Abandoned Coal Mine Land Program Converse County Road 37 funding request include Wyoming Statute 35–11–1202 and Wyoming Abandoned Mine Land Regulations, Chapter VII, of the Wyoming Abandoned Mine Program.

III. Wyoming's Request To Fund the Cost of Converse County Road 37

The Wyoming Department of Environmental Quality submitted to us a grant application dated November 1, 1999. In that application, Wyoming asked for $246,500 to pay for a part of the cost of reconstructing Converse County Road 37. The Governor of Wyoming certified the need and urgency to fund this project prior to completing the State's remaining inventory of non-coal reclamation work, as allowed by section 411(f) of SMCRA. That certification says the project is in a community impacted by coal mining activities. The requested funding is 50 percent of the project's total cost. Money for the balance of the project cost will come from the County's general fund (25 percent), Powder River Coal Company and Kennecott Energy Company (25 percent). The project involves rebuilding 3 miles of County Road 37. This road is one of the busiest roads in the County. The road directly serves the employees of three coal mines. Employees commute daily to these mines by personal vehicles and company buses.

This project will mitigate the impacts of safety hazards associated with the present condition of County Road 37. The Governor's certification states that safety hazards impacting coal mine employees warrant funding of this project before the remaining inventory of non-coal projects are completed.

IV. How We Will Review Wyoming's Grant Application

We will review this grant application using the regulations at 30 CFR 875.15; specifically § 875.15(e) (1) through (7). As stated in those regulations, the application must include the following information: (1) The need or urgency for the activity or the construction of the public facility; (2) the expected impact the project will have on Wyoming's coal or minerals industry; (3) the availability of funding from other sources and, if other funding is provided, its percentage of the total cost involved; (4) documentation from other local, State, and Federal agencies with oversight for such utilities or facilities describing what funding they have available and why their agency is not fully funding this project; (5) the impact on the State, the public, and the minerals industry if the facility is not funded; (6) the reason why this project should be selected before the priority project relating to the protection of the public health and safety or the environment from the damages caused by past mining activities, and (7) an analysis and review of the procedures Wyoming used to notify and involve the public in this request, and a copy of all comments received and their resolution by the State. Wyoming's application for the Converse County Road 37 project contains the information described in these seven subsections.

Section 875.15(f) requires us to evaluate all comments we receive and determine whether the funding meets the requirements of §§ 875.15(e) (1) through (7) described above. It also requires us to determine if the request is in the best interests of the State's AML program. We will approve Wyoming's request to fund this project

if we conclude that it meets all the requirements of 30 CFR 875.15.

V. What To Do If You Want To Comment on the Proposed Project

We are asking for public comments on Wyoming's request for funds to pay for part of the cost of rebuilding Converse County Road 37. You are welcome to comment on the project. If you do, please send us written comments. Make sure your comments are specific and pertain to Wyoming's funding request in the context of the regulations at 30 CFR 875.15 and the provisions of section 411 of SMCRA. You should explain any recommendations you make. If we receive your comments after the time shown under **DATES** or at locations other than the Casper Field Office, we will not necessarily consider them in our final decision or include them in the administrative record.

Dated: November 1, 1999.

Guy Padgett,

Director, Casper Field Office.

[FR Doc. 99–30260 Filed 11–18–99; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than November 29, 1999.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than November 29, 1999.

The petitions filed in this case are available for inspection at the Office of the Director, Office of the Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210.

Signed at Washington, DC, this 18th day of October, 1999.

Grant D. Beale,

Program Manager, Office of Trade Adjustment Assistance.

APPENDIX

[Petitions instituted on 10/18/1999]

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
36,954	Intel Corporation (Wkrs)	Chandler, AZ	10/05/1999	Micro Computer Chips.
36,955	Atlas Foundry and Machine (Wkrs)	Tocoma, WA	10/08/1999	Steel Castings.
36,956	Southeastern Apparel (Comp)	Johnson City, TN	09/15/1999	Jeans.
36,957	COGEMA Mining, Inc (Comp)	Mills, WY	10/04/1999	Uranium Oxide.
36,958	Cone Mills Corp (Comp)	Cliffside, NC	10/05/1999	Denim Fabrics.
36,959	Computer Circuitry Co (Comp)	Grand Prairie, TX	10/07/1999	Printed Circuit Boards.
36,960	CNG Transmission Corp (Comp)	Clarksburg, WV	10/05/1999	Natural Gas.
36,961	General Electric, Meter (Wkrs)	Somersworth, NH	09/29/1999	Singlephase residential meter assembly.
36,962	Ciba Vision Corp (Wkrs)	Johns Creek, GA	09/05/1999	Contact Lenses.
36,963	Lucas Varity Automotive (Comp)	Cincinnati, OH	09/17/1999	Drum Brake Assemblies.
36,964	SmithKline Beecham (Comp)	Piscataway, NJ	10/01/1999	Penicillin.
36,965	Dura Hinge Operations (UAW)	Manchester, MI	10/01/1999	Hinges for Automobile Hood and Deck.
36,966	Magnum Molding, Inc (Comp)	South Paris, ME	09/01/1999	Shoe Heels.
36,967	Blue Falcon Forge, Inc (USWA)	Berick, PA	10/04/1999	Forged Draftlugs for Railroad Cars.
36,968	Pride Pipeline Co. (Wkrs)	Abilene, TX	09/29/1999	Crude Oil.
36,969	Ketchikan Pulp Corp/LPC (Comp)	Ketchikan, AK	10/06/1999	Pulp Mill Products.
36,970	Western States Machine (UAW)	Hamilton, OH	10/05/1999	Sugar Centrifugals.
36,971	United Distillers (Comp)	Allen Park, MI	09/28/1999	Distilled Spirits.
36,972	Dimensions, Inc. (Wrk)	Reading, PA	10/04/1999	Needlepoint, Cross Stitch Kits.
36,973	Heidelberg Publishing (Comp)	Melville, NY	10/05/1999	Prepress-Imagesetting Machines.
36,974	Woods Equipment Co (Comp)	Seguin, TX	10/11/1999	Hydro Buckets.
36,975	Logan and Whaley (Comp)	Lone Star, Tx	09/28/1999	General Warehouse.
36,976	Competitive Edge (UNITE)	Fall River, MA	09/29/1999	Ladies' Skirts, Slacks & Shorts.

[FR Doc. 99–30245 Filed 11–18–99; 8:45 am]

BILLING CODE 4510–30–U

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–36,898]

Procon Products, Murfreesboro, Tennessee; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on September 30, 1999 in response to a worker petition which was filed b a company official on September 20, 1999 on behalf of workers at Procon Products, Murfreesboro, Tennessee.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, DC, this 2th day of November, 1999.

Grant D. Beale,

Program Manager, Office of Trade Adjustment Assistance.

[FR Doc. 99–30247 Filed 11–18–99; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–36,322]

Sheldon Welding & Steel, Inc., Tioga, ND; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on June 1, 1998 in response to a worker petition which was filed on behalf of workers at Sheldon Welding & Steel, Tioga, North Dakota.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation in this case would service no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 2nd day of November 1999.

Grant D. Beale,

Program Manager, Office of Trade Adjustment Assistance.

[FR Doc. 99–30246 Filed 11–18–99; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–36,415]

Zenith Electronics Corp., Microcircuits Division, Chicago, Illinois; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Office of Trade Adjustment Assistance for workers at the Zenith Electronics Corp., Microcircuits Div., Chicago, Illinois. The application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

1TA–W–36,415; Zenith Electronics Corp., Microcircuits Div., Chicago, Illinois (November 3, 1999)

Signed at Washington, DC, this 3rd day of November, 1999.

Grant D. Beale,

Program Manager, Office of Trade Adjustment Assistance.

[FR Doc. 99–30248 Filed 11–18–99; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Job Corps: Preliminary Finding of No Significant Impact (FONSI) for the New Job Corps Center Located at 9 Vandever Avenue, Wilmington, Delaware

AGENCY: Employment and Training Administration, Labor.

ACTION: Preliminary Finding of No Significant Impact (FONSI) for the New Job Corps Center to be located at 9 Vandever Avenue, Wilmington, Delaware.

SUMMARY: Pursuant to the Council on Environmental Quality Regulation (40 CFR Part 1500–08) implementing procedural provisions of the National Environmental Policy Act (NEPA), and the Department of Labor, Employment and Training Administration, Office of Job Corps, in accordance with 29 CFR 11.11(d), gives notice that an Environmental Assessment (EA) has been prepared and the proposed plans for a new Job Corps Center will have no significant environmental impact. This Preliminary Finding of No Significant Impact (FONSI) will be made available for public review and comment for a period of 30 days.

DATES: Comments must be submitted by December 20, 1999.

ADDRESSES: Any comment(s) are to be submitted to Michael O'Malley, Employment and Training Administration, Department of Labor, 200 Constitution Avenue, NW, Room N–4659, Washington, DC, 20210, (202) 219–5468 ext 115 (this is not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Copies of the EA and additional information are available to interested parties by contacting James Bodnar, Regional Director, Region III Office of Job Corps, 3535 Market Street, Room 12220, Philadelphia, PA 19104, (215) 596–6301 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Environmental Assessment (EA) addresses the proposed conversion of a vacated textile manufacturing facility located at 9 Vandever Avenue, 14 blocks from the downtown area of Wilmington, Delaware, for the proposed Wilmington Job Corps Center. The U.S. Department of Labor will not be purchasing the property, but will be leasing the property from the State of Delaware for a 50-year lease term. The building is estimated to have been built in 1884, and has been vacant since 1995. The State of Delaware received title to the subject property in March 1999.

The EA identifies the subject property as an approximately 2.13-acre parcel, including a 3-story building with approximately 113,800-square feet of floor space, and a small paved area. The building covers approximately eighty (80) percent of the subject property parcel, and its walls coincide with the parcel boundaries on the east, south, and west sides. The remaining twenty (20) percent of the site is a paved area along the northern side of the building adjacent to 22nd Street. Next to the subject property are two (2) parking lots owned by the State of Delaware and one (1) commercial parking lot. The proposed Job Corps Center project will include demolition of the existing structure, and construction of a single, two story building which will contain six (6) functions: administration, academic education, vocational education, a cafeteria, culinary arts training, and a maintenance/storage support area . The proposal is for an initial program enrollment of 150 non-resident students.

The construction of the Job Corps Center on this abandoned, developed site would be a positive asset to the area in terms of environmental and

socioeconomic improvements, and long-term productivity. The proposed Job Corps Center will be a new source of employment opportunity for people in the Wilmington, Delaware area. The Job Corps program provides basic education, vocational skills training, work experience, counseling, health care and related support services. This program is designed to graduate students who are ready to participate in the local economy.

The proposed project will not have any significant adverse impact on any natural systems or resources. The existing structure is of minimal historic interest, and is not currently listed on the National Register of Historic Places. The Job Corps, through a future Memorandum of Agreement with the Delaware Historic Preservation Office, proposes to preserve the historic smokestack as a landmark to the neighborhood. All new construction for this project will comply with applicable historic preservation guidelines and incorporate known architectural historical features of the surrounding neighborhood. There are no known areas of archaeological significance on or near the property, and no state or federal threatened or endangered species (proposed or listed) have been located on the subject property.

The subject property is located at the northwest fringe of the Central Business District (CBD) of the City of Wilmington. Air quality and noise levels should not be affected by the proposed development project, except possibly during construction and renovation. All construction and renovation activities will be conducted in accordance with applicable noise and air pollution regulations, and all pollution sources will be permitted in accordance with applicable pollution control requirements. The proposed Job Corps Center will not significantly increase vehicle traffic in the vicinity.

The proposed project will not have any significant adverse impact on the surrounding water, sewer, and storm water utilities infrastructure. The City of Wilmington Department of Public Works provides water service to the subject property. The water distribution system at the site is in good condition, with approximately fifty (50) pounds of pressure. The existing water lines should be adequate to meet the needs of the proposed Job Corps Center. All wastewater from the existing facility is discharged to a sewer system operated by the City of Wilmington Sewer Authority. The existing sanitary sewer system is in good condition, and should be adequate to meet the needs of the proposed Job Corps Center. Storm water runoff from parking lots, sidewalks, and other structures on the new Job Corps Center will be managed during construction and operation of the proposed project in accordance with the requirements of the Department of Natural Resources and Environmental Control (DNREC), Division of Soil & Water Conservation. Storm water runoff from the site is not anticipated to adversely impact area surface water quality.

Solid waste disposal in Delaware is regulated by the DNREC, Division of Air & Waste Management, Solid Waste Management Branch. There are currently three (3) sanitary landfills and seven (7) industrial landfills in Delaware, which will provide sufficient waste disposal capacity for the proposed project. Solid waste generated during construction and operation of the Job Corps Center will be removed by a private transporter for disposal at an approved landfill facility.

Connectiv Power Delivery (formerly Delmarva Power and Light Company) provides electrical service to the subject project. Connectiv Power Delivery is one of two corporations that supply natural gas in the New Castle County. Both of these utilities have distribution lines in the vicinity, which have sufficient capacity to handle the service demand created by the Job Corps Center. The demand for utility services is not expected to have a significant adverse affect on the environment.

Several major highways connect the Greater Wilmington area with nearby metropolitan cities. Amtrak provides daily passenger rail service, with connections in Wilmington, to points along the Northeast corridor. Bus transportation is provided by the Delaware Administration for Regional Transit (DART). DART provides twenty-six (26) separate routes servicing all parts of the City of Wilmington and most areas of northern New Castle County. Many of the routes link the suburbs with the CBD, and provide peak rush hour service especially beneficial to suburbanites who work in the City. A second transit authority, the Delaware Authority for Specialized Transit (DAST) provides a fleet of buses serving the transportation needs of the handicapped statewide. No significant adverse affects are expected for the transportation system for the City of Wilmington.

No significant adverse affects should be expected by the local medical, emergency, fire and police facilities. There are several primary providers of medical services in the City of Wilmington. The primary medical provider located closest to the subject property is the Medical Center of Delaware, located approximately fifteen (15) blocks from the facility. There are also private medical facilities located in the CBD.

Security services at the Job Corps will be provided by the center's staff, with two (2) personnel on the day shift, three (3) on the evening shift, and two (2) on the night shift. There is a City of Wilmington Police Station approximately fifteen (15) blocks from the subject property. The closest fire station to the project site is the Wilmington Fire Department, Station #4 located within one (1) block of the facility. The Emergency Medical Services (EMS) is a component of the Emergency Services Branch of the New Castle County Police Department. The agency provides paramedic services to the entire 437 square miles of the County, including the City of Wilmington. The EMS is a full time department providing 24-hour service. All emergency services in Wilmington are adequate for the proposed project.

The proposed project will not have a significant adverse sociological affect on the City of Wilmington. Similarly, the proposed project will not have a significant adverse affect on demographics and socioeconomic characteristics of the area. This area offers numerous educational and recreational opportunities for the proposed student population.

The alternatives considered in the preparation of this FONSI were as follows: (1) No Action; (2) Construction at an Alternate Site; and (3) Continue Construction as Proposed. The ''No Action'' alternative was not selected because the U.S. Department of Labor would not meet their goal of establishing new Job Corps Centers in under-served regions of the United States. The ''Construction at an Alternate Site'' alternative was not selected because the Wilmington site was the only proposed facility in the State of Delaware, and no alternative sites are available for construction within the State of Delaware.

Due to the suitability of the proposed site for establishment of a new Job Corps Center, and the absence of any identified significant adverse environmental impacts from locating a Job Corps Center on the subject property, the ''Continue Construction as Proposed'' alternative was selected.

Based on the information gathered during the preparation of the EA, no environmental liabilities, current or historical, were found to exist on the proposed Job Corps Center site. The construction of the Job Corps Center at the existing building located at 9

Vandever Avenue in Wilmington, Delaware will not create any significant adverse impacts on the environment.

Dated at Washington, DC, this 15th day of November, 1999.

Mary Silva,

National Director of Job Corps.

[FR Doc. 99–30243 Filed 11–18–99; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA—03416]

Diversified Trucking, a Former Roadmaster Co., Olney, Illinois; Notice of Termination of Investigation

Pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182) concerning transitional adjustment assistance, hereinafter called NAFTA–TAA and in accordance with section 250(a), Subchapter 2, Title II, of the Trade Act of 1974, as amended (19 USC 2331), an investigation was initiated on September 2, 1999, in response to a petition filed on the same date on behalf of workers of Diversified Trucking, a former Roadmaster Company, located in Olney, Illinois.

All workers were separated from the subject firm more than one year prior to the date of the petition. Section 223(b)(1) of the Act of 1974, as amended, specifies that no certification may apply to any workers whose last separation occurred more than one year before the date of the petition. This requirement is applicable to NAFTA–TAA petition. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, DC, this 4th day of November, 1999

Grant D. Beale,

Program Manager, Office of Trade Adjustment Assistance.

[FR Doc. 99–30250 Filed 11–18–99; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–03324]

Modine Aftermarket Holdings, Inc., Including Leased Workers of Remedy Temps, Merced, California; Amended Certification Regarding Eligibility to Apply for NAFTA-Transitional Adjustment Assistance

In accordance with section 250(A), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974 (19 U.S.C. 2273), the Department of Labor issued a Certification for NAFTA Transitional Adjustment Assistance on August 27, 1999, applicable to workers of Modine Aftermarket Holdings, Inc., Merced, California. The notice was published in the **Federal Register** on September 29, 1999 (64 FR 52540).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. New information shows that some workers of Modine Aftermarket Holdings, Inc., were leased from Remedy Temps to product radiators for automobiles and trucks at the Merced, California facility.

Based on these findings, the Department is amending the certification to include workers of Remedy Temps, Merced, California leased to Modine Aftermarket Holdings, Inc., Merced, California.

The intent of the Department's certification is to include all workers of Modine Aftermarket Holdings, Inc., adversely affected by imports from Mexico and Canada.

The amended notice applicable to NAFTA–03324 is hereby issued as follows:

All workers of Modine Aftermarket Holdings, Inc., Merced, California and leased workers of Remedy Temps, Merced, California engaged in employment related to the production of radiators for automobiles and trucks for Modine Aftermarket Holdings, Inc., Merced, California who became totally or partially separated from employment on or after July 19, 1998 through August 27, 2001 are eligible to apply for NAFTA–TAA under section 250 of the Trade Act of 1974.

Signed at Washington, DC, this 30 day of November 1999.

Grant D. Beale,

Program Manager, Office of Trade Adjustment Assistance.

[FR Doc. 99–30251 Filed 11–18–99; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA 3498]

Southeastern Apparel Finishing, Inc., Johnson City, TN; Notice of Termination of investigation

Pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103–183) concerning transitional adjustment assistance, hereinafter called NAFTA–TAA and in accordance with section 250(a), Subchapter 2, Title II, of the Trade Act of 1974, as amended (19 USC 2331), an investigation was initiated on October 8, 1999, in response to a petition filed on the same date on behalf of workers of Southeastern Apparel finishing, Inc., Johnson City, Tennessee.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, DC. this 4th day of November, 1999.

Grant D. Beale,

Program Manager, Office of Trade Adjustment Assistance.

[FR Doc. 99–30249 Filed 11–18–99; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment Standards Administration Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determine to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1,

appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register,** or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Withdrawn General Wage Determination Decision

This is to advise all interested parties that the Department of Labor is withdrawing from the date of this notice, General Wage Determination No. PA990059 dated March 12, 1999. See PA990062.

Contracts for which bids have been opened shall not be affected by this notice. Also, consistent with 29 CFR 1.6(c)(i)(A), when the opening of bids is less than ten (10) days from the date of this notice, this action shall be effective unless the agency finds that there is insufficient time to notify bidders of the change and the finding is documented in the contract file.

New General Wage Determination Decisions

The number of the decisions added to the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts'' are listed by Volumes and States:

Volume II

WEST VIRGINIA
WV990011 (Nov. 19, 1999)
WV990012 (Nov. 19, 1999)

Volume III

MISSISSIPPI
MS990061 (Nov. 19, 1999)
MS990062 (Nov. 19, 1999)

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

MASSACHUSETTS
MA990003 (Mar. 12, 1999)
MA990005 (Mar. 12, 1999)
MA990006 (Mar. 12, 1999)
MA990009 (Mar. 12, 1999)
MA990012 (Mar. 12, 1999)
MA990013 (Mar. 12, 1999)
MA990019 (Mar. 12, 1999)
MA990020 (Mar. 12, 1999)
MA990021 (Mar. 12, 1999)
NEW YORK
NY990018 (Mar. 12, 1999)
VERMONT
VT990002 (Mar. 12, 1999)
VT990026 (Mar. 12, 1999)
VT990027 (Mar. 12, 1999)
VT990028 (Mar. 12, 1999)
VT990029 (Mar. 12, 1999)
VT990030 (Mar. 12, 1999)
VT990031 (Mar. 12, 1999)
VT990032 (Mar. 12, 1999)
VT990033 (Mar. 12, 1999)
VT990034 (Mar. 12, 1999)
VT990035 (Mar. 12, 1999)
VT990036 (Mar. 12, 1999)
VT990037 (Mar. 12, 1999)
VT990038 (Mar. 12, 1999)

Volume II

PENNSYLVANIA
PA990001 (Mar. 12, 1999)
PA990002 (Mar. 12, 1999)
PA990003 (Mar. 12, 1999)
PA990011 (Mar. 12, 1999)
PA990017 (Mar. 12, 1999)
PA990018 (Mar. 12, 1999)
PA990020 (Mar. 12, 1999)
PA990027 (Mar. 12, 1999)
PA990038 (Mar. 12, 1999)
PA990043 (Mar. 12, 1999)
PA990051 (Mar. 12, 1999)
PA990053 (Mar. 12, 1999)
PA990055 (Mar. 12, 1999)
PA990062 (Mar. 12, 1999)
West Virginia
WV990002 (Mar. 12, 1999)
WV990003 (Mar. 12, 1999)
WV990006 (Mar. 12, 1999)

Volume III

Florida
FL990001 (Mar. 12, 1999)
FL990002 (Mar. 12, 1999)
FL990017 (Mar. 12, 1999)
FL990066 (Mar. 12, 1999)
Georgia
GA990004 (Mar. 12, 1999)
GA990023 (Mar. 12, 1999)
GA990044 (Mar. 12, 1999)
GA990050 (Mar. 12, 1999)
GA990065 (Mar. 12, 1999)
GA990073 (Mar. 12, 1999)
GA990093 (Mar. 12, 1999)
GA990094 (Mar. 12, 1999)
Mississippi
MS990001 (Mar. 12, 1999)
MS990055 (Mar. 12, 1999)
MS990058 (Mar. 12, 1999)

Volume IV

Michigan
MI990003 (Mar. 12, 1999)
MI990012 (Mar. 12, 1999)
MI990064 (Mar. 12, 1999)

Volume V

Kansas
KS990006 (Mar. 12, 1999)
KS990008 (Mar. 12, 1999)
KS990012 (Mar. 12, 1999)
KS990013 (Mar. 12, 1999)
KS990015 (Mar. 12, 1999)
KS990018 (Mar. 12, 1999)
KS990019 (Mar. 12, 1999)
KS990022 (Mar. 12, 1999)
KS990069 (Mar. 12, 1999)
KS990070 (Mar. 12, 1999)
Nebraska
NE990001 (Mar. 12, 1999)
NE990019 (Mar. 12, 1999)
NE990038 (Mar. 12, 1999)

Volume VI

Colorado
CO990001 (Mar. 12, 1999)
CO990005 (Mar. 12, 1999)
CO990006 (Mar. 12, 1999)
CO990008 (Mar. 12, 1999)

CO990009 (Mar. 12, 1999)
CO990010 (Mar. 12, 1999)
CO990011 (Mar. 12, 1999)
CO990016 (Mar. 12, 1999)
CO990018 (Mar. 12, 1999)
CO990025 (Mar. 12, 1999)
Idaho
ID990003 (Mar. 12, 1999)
Oregon
OR990001 (Mar. 12, 1999)
Washington
WA990005 (Mar. 12, 1999)

Volume VII

California
CA990031 (Mar. 12, 1999)
CA990034 (Mar. 12, 1999)
CA990037 (Mar. 12, 1999)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts.'' This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

The general wage determinations issued under the Davis-Bacon and related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the seven separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Signed at Washington, DC, this 10th day of November, 1999.

Carl J. Poleskey,

Chief, Branch of Construction Wage Determinations.

[FR Doc. 99–29978 Filed 11–18–99; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Proposed Information Collection Request Submitted for Public Comment and Recommendations; Notification of Commencement of Operations and Closing of Mines

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments concerning the proposed extension of the information collection related to the Notification of Commencement of Operations and Closing of Mines. MSHA is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

A copy of the proposed information collection request can be obtained by contacting the employee listed below in the For Further Information Contact section of this notice.

DATES: Submit comments on or before January 18, 2000.

ADDRESSES: Send comments to Diane P. Hill, Program Analysis Officer, Office of Program Evaluation and Information Resources, 4015 Wilson Boulevard, Room 715, Arlington, VA 22203–1984. Commenters are encouraged to send their comments on a computer disk, or via Internet E-mail to dhill@msha.gov, along with an original printed copy. Ms. Hill can be reached at (703) 235–1470 (voice), or (703) 235–1563 (facsimile).

FOR FURTHER INFORMATION CONTACT: Diane P. Hill, Program Analysis Officer, Office of Program Evaluation and Information Resources, U.S. Department of Labor, Mine Safety and Health Administration, Room 719, 4015 Wilson Boulevard, Arlington, VA 22203–1984. Ms. Hill can be reached at dhill@msha.gov (Internet E-mail), (703) 235–1470 (voice), or (703) 235–1563 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Under 30 CFR 56.1000 and 57.1000, operators of metal and nonmetal mines must notify the Mine Safety and Health Administration (MSHA) when the operation of a mine will commence or when a mine is closed. Openings and closings of mines are dictated by the economic strength of the commodity mined, and by weather conditions which prevail at the mine site during various seasons.

MSHA must be aware of openings and closings so that its resources can be used efficiently in achieving the requirements of the Mine Act.

II. Current Actions

Section 103(a) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 813, requires that each underground mine be inspected in its entirety at least four times a year, and each surface mine at least two times per year. Mines which operate only during warmer weather must be scheduled for inspection during the spring, summer and autumn seasons. Mines are sometimes located a great distance from MSHA field offices and the notification required by this standard precludes wasted time and trips.

Type of Review: Extension.

Agency: Mine Safety and Health Administration.

Title: Notification of Commencement of Operations and Closing of Mines.

OMB Number: 1219–0092.

Affected Public: Business or other for-profit.

Cite/Reference/Form/etc: 30 CFR 56.1000 and 57.1000.

Total Respondents: 2,300.

Frequency: On occasion.

Total Responses: 2,070.

Average Time per Response: 0.125 hours.

Total Burden Hours: 259 hours.

Total Burden Cost (capital/startup):

Total Burden Cost (operating/maintaining): $1,438.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: November 12, 1999.

George M. Fesak,

Director, Program Evaluation and Information Resources.

[FR Doc. 99–30244 Filed 11–18–99; 8:45 am]

BILLING CODE 4510–43–M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Advisory Committee on the Records of Congress; Meeting

AGENCY: National Archives and Records Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Archives and Records Administration (NARA) announces a meeting of the Advisory Committee on the Records of Congress. The committee advises NARA on the full range of programs, policies, and plans for the Center for Legislative Archives in the Office of Records Services.

DATES: December 6, 1999, from 10:00 a.m. to 11:30 a.m.

ADDRESSES: United States Capitol Building, Room S–211.

FOR FURTHER INFORMATION CONTACT: Michael L. Gillette, Director, Center for Legislative Archives, (202) 501–5350.

SUPPLEMENTARY INFORMATION:

Agenda

Third Report to Congress
Treasures of Congress Exhibition
Update—Center for Legislative Archives
Other current issues and new business

The meeting is open to the public.

Dated: November 15, 1999.

Mary Ann Hadyka,

Committee Management Officer.

[FR Doc. 99–30195 Filed 11–18–99; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL EDUCATION GOALS PANEL

Meeting

AGENCY: National Education Goals Panel.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the date and location of a forthcoming meeting of the National Education Goals Panel. This notice also describes the functions of the Panel.

DATE AND TIME: Wednesday, December 1, 1999 from 1:00 p.m. to 5:00 p.m.

ADDRESSES: J.W. Marriott Hotel, 1331 Pennsylvania Avenue, NW, SALON 1, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Ken Nelson, Executive Director, 1255 22nd Street, NW, Suite 502, Washington, DC 20037. Telephone: (202) 724–0015.

SUMMARY: The National Education Goals Panel was established to monitor, measure and report state and national progress toward achieving the eight National Education Goals, and report to the states and the Nation on that progress.

Agenda Items

The meeting of the Panel is open to the public. The meeting is a 10th Anniversary Conference with presentations to the Panel beginning at 1:00 p.m. about the future ''Big Issues'' of education. At 3:30 p.m. Panel members will engage the presenters and audience in a public hearing on the future role that the Goals and the Panel can play in addressing these big issues.

Dated: November 15, 1999.

Ken Nelson,

Executive Director, National Education Goals Panel.

[FR Doc. 99–30217 Filed 11–18–99; 8:45 am]

BILLING CODE 4010–01–M

NATIONAL EDUCATION GOALS PANEL

Meeting

AGENCY: National Education Goals Panel.

ACTION: Notice of meeting/press conference.

SUMMARY: This notice sets forth the date and location of a forthcoming meeting of the National Education Goals Panel. This notice also describes the functions of the Panel.

DATES AND TIME: Thursday, December 2, 1998, 9:30 a.m. to 12:00 p.m.

ADDRESSES: National, Press Club, 529 14th Street, NW, Washington, DC 20045. (National Education Goals Panel Meeting, 9:30 a.m.–10:45 a.m. to 12:00 p.m., Ballroom.)

FOR FURTHER INFORMATION CONTACT: Ken Nelson, Executive Director, 1255 22d Street, NW, Suite 502, Washington, DC 20037. Telephone: (202) 724–0015.

SUMMARY: The National Education Goals Panel was established to monitor, measure and report state and national progress toward achieving the eight National Education Goals, and report to the states and the Nation on that progress.

Agenda Items

The meeting of the Panel is open to the public. The National Education Goals Panel will convene a series of events on December 2 at the National Press Club. From 9:30 a.m. to 10:45 a.m. the Panel will discuss recommendations of the 10th Anniversary Conference and adopt an Action Statement. The Panel will also characterize Panel Field Hearings: ''Strategies for Achieving the Goals.'' From 11 to 12 there will be a press conference announcing the release of two new reports, Building a Nation of Learners 1999 and the Data Volume for the National Education Goals, 1999. The Building a Nation of Learner, 1999 report will illustrate the nation's progress in each of the 8 National Education Goal areas. The Data Volume will provide detailed information about each state's performance towards attaining the National Education Goals.

Dated: November 15, 1999.

Ken Nelson,

Executive Director, National Education Goals Panel.

[FR Doc. 99–30218 Filed 11–18–99; 8:45 am]

BILLING CODE 4010–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–244]

Rochester Gas and Electric Corporation; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR–18 issued to Rochester Gas and Electric Corporation (the licensee) for operation of the R.E. Ginna Nuclear Power Plant located in Wayne County, New York.

The proposed amendment would change the footnote to the Improved

Technical Specifications associated with the Design Features Fuel Storage Specification 4.3.1.1.b which required that 2300 ppm boron be maintained in the Spent Fuel Pool until December 31, 1999. The footnote would be changed to require 2300 ppm boron be maintained until June 30, 2001.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Evaluation of Administrative Change

The administrative change associated with the revision of the date specified in the Specification 4.3.1.1.b note associated with maintaining spent fuel pool boron concentration [greater than or equal to] 2300 ppm at all times until a permanent resolution can be implemented does not involve a significant hazards consideration as discussed below:

(1) Operation of Ginna Station in accordance with the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated. The change revises the required completion date for resolution of a boraflex degradation issue. As described in the bases for LCO [limiting condition for operation] 3.7.12, increases in spent fuel pool temperature, with the corresponding decrease in water density and void formation from boiling, will generally result in an decrease in reactivity due to the decrease in moderation effects. The only exception are temperature bands where positive reactivity is added as a result of the high boron concentration. This effect is bounded by the reactivity added as a result of a misloaded fuel assembly. With respect to the more limiting dropped fuel assembly accidents, boraflex neutron absorber panels were originally assumed in the criticality analysis. Requiring a high concentration of soluble boron in place of boraflex panels ensures that the spent fuel pool remains subcritical with k_{eff} [less than or equal to] 0.95 for these accidents. Fuel assembly movement will continue to be controlled in accordance with plant procedures and LCO 3.7.13 which specifies limits on fuel assembly storage locations. Periodic surveillances of boron concentration are required every 7 days with level verified every 7 days during fuel movement per LCO 3.7.11. Due to the large inventory within the spent fuel pool, dilution of the soluble boron within the pool is very unlikely without being detected by operations personnel during auxiliary operator rounds or available level detection systems. There is also a large margin between the analyzed boron concentration to maintain the pool subcritical k_{eff} [less than or equal to] 0.95 and the current required value. The extension of the date does not invalidate this conclusion. Therefore, the probability or consequences of an accident previously evaluated is not significantly increased.

(2) Operation of Ginna Station in accordance with the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated. Revising the date for requiring that 2300 ppm boron be maintained in the spent fuel pool, to address any potential dissolution of boraflex in neutron absorber panels, does not create the possibility of a new or different kind of accident since the spent fuel pool is required to be maintained with a high boron concentration. Assuming a boron dilution event to the level required to reach $k_{eff} > 0.95$ conditions within the spent fuel pool would require either overfill of the pool or a controlled feed and bleed process with unborated water. In both cases, more than 105,000 gallons of unborated water would be required to reach $k_{eff} > 0.95$. There is no source of unborated water of this size available to reach the spent fuel pool under procedural control or via a pipe break other than a fire water system pipe break or SW [service water] leak through the spent fuel pool heat exchangers. However, there are numerous alarms available within the control room to indicate this condition including high spent fuel pool water level and sump pump actuations within the residual heat removal pump pit (lowest location in the Auxiliary Building). Auxiliary operators also perform regularly scheduled tours within the Auxiliary Building. This provides sufficient time to terminate the event such that there is no credible spent fuel pool dilution accident. Therefore, the possibility for a new or different kind of accident from any accident previously evaluated is not created.

(3) Operation of Ginna Station in accordance with the proposed change does not involve a significant reduction in a margin of safety. High levels of soluble boron in the spent fuel pool provides a significant negative reactivity such that k_{eff} is maintained [less than or equal to] 0.95. The proposed surveillance frequency will ensure that the necessary boron concentration is maintained. A boron dilution event which would remove the soluble boron from the pool has been shown to not be credible. Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D59, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By December 20, 1999, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR part 2. Interested persons should

consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site (http://www.nrc.gov). If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to Nicholas S. Reynolds, Winston & Strawn, 1400 L Street, NW., Washington, DC 20005, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated October 20, 1999, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site (http://www.nrc.gov).

Dated at Rockville, Maryland, this 15th day of November, 1999.

For the Nuclear Regulatory Commission.

Guy S. Vissing,

Senior Project Manager, Project Directorate, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 99–30226 Filed 11–18–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Meeting on the Agencywide Documents Access and Management System

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of meeting.

SUMMARY: The NRC will be presenting an overview on the Agencywide Documents Access and Management System (ADAMS). The purpose of the meeting is to provide information on ADAMS to industry licensing officials who are involved in the day to day processing of licensing actions. The meeting will consist of three key areas of information: (1) Overview of the ADAMS Program, (2) Public Access to ADAMS, and (3) Electronic Information Exchange. This information will provide the background for a workshop to be held early next year. The workshop, which is currently expected to be held in late February or early March, will consist of working groups discussing the issue of living documents and any issues raised as a result of the December 10, 1999, meeting. The meeting is open to the public and any interested parties may attend.

DATES: December 10, 1999, from 8:30 a.m. to 1:00 p.m.

LOCATION: Two White Flint North Auditorium, 11545 Rockville Pike, Rockville, Maryland 20852–2738.

FOR FURTHER INFORMATION CONTACT:

Marsha Gamberoni, Mail Stop O–8 E1, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852–2738; Telephone:

(301) 415–3024; Internet: *MKG@NRC.GOV*
or
Lynn Scattolini, Mail Stop T–6 F15, U.S. Nuclear Regulatory Commission, 11545 Rockville Pike, Rockville, Maryland 20852–2738; Telephone: (301) 415–8729; Internet: *LBS@NRC.GOV*
or
Aby Mohseni, Mail Stop T–8 A23, U.S. Nuclear Regulatory Commission, 11545 Rockville Pike, Rockville, Maryland 20852–2738; Telephone: (301) 415–6409; Internet: *ASM@NRC.GOV*

Dated at Rockville, Maryland, this 15th day of November 1999.

For the Nuclear Regulatory Commission.

Marsha Gamberoni,

Technical Assistant, Division of Licensing Project Management Office of Nuclear Reactor Regulation.

[FR Doc. 99–30225 Filed 11–18–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Lessons Learned From Maintenance Rule Baseline Inspections

Availability of NUREG–1648

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Availability.

SUMMARY: The Nuclear Regulatory Commission announces the completion and availability of NUREG–1648, ''Lessons Learned From Maintenance Rule Baseline Inspections,'' dated October, 1999.

ADDRESSES: Copies of NUREG–1648 may be obtained from the Reproduction and Distribution Services Section, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001. Copies are also available electronically. See ''Electronic Access.'' which follows. A copy of the document is also available for inspection and/or copying for a fee in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC 20555–0001.

FOR FURTHER INFORMATION CONTACT: Richard Correia, Division of Inspection Program Management, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone: 301–415–1009.

SUPPLEMENTARY INFORMATION: On November 1, 1999, the NRC announced the availability of NUREG–1648, ''Lessons Learned From Maintenance Rule Baseline Inspections,'' dated October 1999. This NUREG report provides details concerning lessons learned from implementing the NRC's first risk-informed performance-based regulation, the maintenance rule, 10 CFR 50.65. Licensees can use the lessons learned information in this document to enhance and improve their maintenance rule programs.

NUREG–1648 is now available for use by licensees and other NRC staff. It supplements the lessons learned information previously found in NUREG–1526, ''Lessons Learned From Early Implementation of the Maintenance Rule at Nine Nuclear Power Plants,'' dated June, 1995.

The risk-informed, performance-based approach of implementing 10 CFR 50.65 and the guidance documents that implement this approach, NUMARC 93–01, ''Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants,'' as endorsed by Regulatory Guide 1.160, ''Monitoring the Effectiveness of Maintenance at Nuclear Power Plants,'' gives licensees flexibility in monitoring the effectiveness of maintenance at nuclear power plants. During the NRC maintenance rule baseline inspections, the inspection teams also found that many licensees used unique and diverse methods to implement the maintenance rule that went beyond the guidance contained in the documents noted above. Licensees can use these lessons learned methods to enhance and improve their existing maintenance rule programs.

Electronic Access

NUREG–1648 is also available electronically by visiting NRC's Public Web Site at (http://www.nrc.gov), choose the ''Nuclear Reactors'' page of the site and then choose the ''Maintenance Rule.'' The Maintenance Rule Home Page may also be accessed directly by using the uniform resource locator (URL) at (*http://www.nrc.gov/NRR/mrule/mrhome.htm*). The user must ensure that the URL is typed exactly as shown because the Web server file name convention is case sensitive.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget.

Dated at Rockville, Maryland, this 1st day of November, 1999.

For the Nuclear Regulatory Commission.

Bruce A. Boger,

Director, Division of Inspection Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 99–30227 Filed 11–18–99; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Proposed Collection, Comment Request; SF 86 Related Certification Form

AGENCY: Office of Personnel Management.

ACTION: Proposed collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13) and 5 CFR 1320.5(a)(I)(vi), this notice announces that OPM intends to submit to the Office of Management and Budget (OMB) a request for clearance of an information collection device and solicit comments on it.

The Standard Form 86 (SF 86), Questionnaire for National Security Positions, is completed by persons performing, or seeking to perform, national security duties for the Federal Government. This information collection is used by the Office of Personnel Management and by other Federal agencies to initiate the background investigation required to determine placement in national security positions in accordance with 42 U.S.C. 2165, 22 U.S.C. 2585, E.O. 10450, Security Requirements for Government Employment, issued April 27, 1953 and E.O. 12968, Access to Classified Information, issued August 2, 1995.

There are many situations where individuals are required to fill out a new SF 86 when the sole purpose is to determine if any information on a previously executed SF 86 has changed. This requires extensive execution even if nothing has changed.

The information collection being proposed is a certification device (tentatively titled SF 86C) that allows the reporting of changes in previously reported information on the SF 86. This certification will be in lieu of executing an SF 86 and will allow the individual to indicate that there have been no changes in the data provided on the most recently filed SF 86, or, where there are changes, to provide the new/changed information. No investigation will be initiated based solely on the execution of this form. However,

information provided on this form may provide cause to require execution of a new SF 86 in order for an investigation to be scheduled. This is no different than if an SF 86 had been used in the first place to ''update'' information.

This request for comments is *not* meant to elicit comments on the questions as they appear on the SF 86. This certification device will ask for nothing more, or less, than is asked for on the current SF 86 which is approved for use through June 30, 2001.

The number of respondents annually who are not Federal employees is expected to be 75,000 with total reporting hours of 25,000.

Comments are particularly invited on:

—Whether this collection device has a practical utility;

—Whether our estimate of the public burden of this collection device is accurate and based on valid assumptions and methodology; and,

—Ways we can minimize the burden of collection of information on those who respond through the use of appropriate technological collection techniques or other forms of information technology.

To obtain copies of this proposal, please contact Mary Beth Smith-Toomey at (202) 606–8358 or by E-Mail to *mbtoomey@opm.gov*

DATES: Comments on this proposal should be received on or before January 18, 2000.

ADDRESSES: Submit or deliver comments on this proposal to: John H. Crandell, Investigations Service, Office of Personnel Management, Room 5416, 1900 E Street, NW, Washington, DC 20415–4000 or via fax to 202–606–2390, or by E-Mail to *jhcrande@OPM.gov*.

U.S. Office of Personnel Management.

Janice R. Lachance,

Director.

[FR Doc. 99–30219 Filed 11–18–99; 8:45 am]

BILLING CODE 6325–01–P

OFFICE OF PERSONNEL MANAGEMENT

The Combined Federal Campaign

AGENCY: Office of Personnel Management.

ACTION: Notice of limitation on the recognition of national federations.

SUMMARY: Pursuant to the Combined Federal Campaign (CFC) regulations at 5 CFR 950.301(a) which states that ''the Director may from time to time place a moratorium on the recognition of national federations'', I hereby establish such action for a one year period, beginning with the national application process for the year 2000 campaign.

This moratorium will provide an opportunity for the Office of Personnel Management to strengthen the monitoring and auditing process, as well as capability to ensure that national federations meet and operate in accordance with the public accountability standards of 5 CFR 950.203 and conform to the requirements of 5 CFR 950.301. This action does not prohibit any charity from applying to the CFC national listing as an unaffiliated organization, or from applying to the 20 existing federations, which currently represent 964 of the 1317 national charitable organizations. A list of the existing federations is attached.

EFFECTIVE DATE: Year 2000 Campaign.

CONTACT PERSON FOR MORE INFORMATION: Mara T. Patermaster, Director, Combined Federal Campaign Operations, Office of Personnel Management, Theodore Roosevelt Building, 1900 E Street, NW., Room 5450, Washington, DC 20415–0001, (202) 606–2564.

Office of Personnel Management.

Janice R. Lachance,

Director.

National CFC Federations

American Red Cross
America's Charities
Animal Funds of America
Children's Charities of America
Christian Service Organizations of America
Community Health Charities
Conservation and Preservation Charities of America
Do Unto Others: America's Emergency Relief, Development, and Humanitarian Outreach Charities
Earth Share
Educate America: The Education, School Support & Scholarship Funds Coalition
Health and Medical Research Charities of America
Human and Civil Rights Organizations of America
Human Service Charities of America
International Service Agencies
Medical Research Agencies of America
Military, Veterans and Patriotic Service Organizations
National Black United Federation of Charities
United Way of America
United Service Organizations
Women, Children, and Family Service Charities of America

[FR Doc. 99–30205 Filed 11–18–99; 8:45 am]

BILLING CODE 6325–01–U

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–27100]

Filings Under the Public Utility Holding Company Act of 1935, as Amended (''Act'')

November 12, 1999.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated under the Act. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments is/are available for public inspection through the Commission's Branch of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by December 6, 1999, to the Secretary, Securities and Exchange Commission, Washington, DC 20549–0609, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of facts or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After December 6, 1999, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Monongahela Power Company (70–9567)

Monongahela Power Company (''Monongahela Power''), 1310 Fairmont Avenue, Fairmont, West Virginia 23219, a wholly owned public utility subsidiary of Allegheny Energy, Inc. (''Allegheny''), 10435 Downsville Pike, Hagerstown, Maryland 21740–1766, a registered holding company, has filed an application under section 11(b) of the Act and rule 54 under the Act.

Monongahela Power proposes to acquire and retain all of the assets and properties owned by UtiliCorp United Inc. (''UtiliCorp'') and used in its utility business in West Virginia (''Transaction''). Allegheny and UtiliCorp entered into an agreement whereby Monogahela Power, as Allegheny's designated affiliate, will purchase all the utility assets of UtiliCorp's West Virginia Power

division (''West Virginia Power''). This purchase of utility assets is subject to approval by the West Virginia Public Service Commission. The proposed purchase price of West Virginia Power is approximately $75 million.[1] The purchase price is subject to adjustment shortly after closing, based upon the closing date balance sheet.

UtiliCorp, a combination gas and electric utility based in Kansas City, Missouri, provides electric and gas utility services to more than three million electric and gas customers, primarily in the Midwest. West Virginia Power is UtiliCorp's combination gas and electric division operating only in West Virginia and has its principal place of business in Fairlea, West Virginia. As of October, 1999, West Virginia Power employed about 120 people. For the twelve months ended December 31, 1998, UtiliCorp's revenues were approximately $12.5 billion. West Virginia Power contributed $51.9 million of those revenues—$28.2 million from electric sales and $23.7 million from gas sales.

West Virginia Power provides electric service to approximately 26,000 customers. West Virginia Power's electric assets and electric service territory are located in five counties in southeastern West Virginia. West Virginia Power's electric distribution lines cover approximately 1,989 miles in a 1,360 square mile service area.

West Virginia Power's natural gas assets and service territory serve approximately 24,000 customers in relatively small pockets in central and south-central West Virginia in areas within or relatively close to Applicant's existing service territory. West Virginia Power's gas service territory includes approximately 670 miles of gas pipeline in a 500 square mile service area. It is stated that following completion of the proposed Transaction, the gas utility operations of the Applicant will be substantially smaller than the gas utility operations of Applicant's competitors in the region.

Monongahela Power currently provides electric service to approximately 325,000 West Virginia customers. Its revenues were approximately $645 million for the twelve months ended September 30, 1999. Its service territory is contiguous to West Virginia Power's service territory. Monongahela Power intends to create two new divisions for this acquisition: one division will encompass the UtiliCorp West Virginia electric assets and another, separate division will encompass the UtiliCorp West Virginia gas assets.

[1] This acquisition price approximates the book value of the assets.

Entergy Corporation (70–8903)

Entergy Corporation (''Entergy''), 639 Loyola Avenue, New Orleans 70113, a registered holding company, has filed a post-effective amendment under sections 6(a) and 7 of the Act and rule 54 under the Act to a declaration previously filed under the Act.

By order dated February 26, 1997 (HCAR No. 26674) (''Order''), the Commission authorized Entergy to enter into a credit agreement (''Credit Agreement'') with one or more banks. The Order permitted Entergy to borrow up to an aggregate outstanding principal amount of $500 million in short-term notes through December 31, 2002 (''Notes''), using various rate options having limits on the margins payable over the rates underlying those options.

Entergy now requests authority to change the interest rate terms approved in the Order. It now proposes to pay interest on the Notes at rates that will exceed those paid by companies on debt securities of similar credit quality having similar terms, conditions and maturities.

The Southern Company (70–8277)

The Southern Company (''Southern''), 270 Peachtree Street, N.W., Atlanta, Georgia 30303, a registered holding company, has filed a post-effective amendment under sections 6(a) and 7 of the Act and rules 53 and 54 under the Act to an application-declaration previously filed under the Act.

By order dated August 3, 1995 (HCAR No. 26349) (''Order''), among other things, Southern was authorized to issue and sell in one or more transactions, through December 31, 1999, up to 25 million shares of its common stock, $5 par value (''Common''). As of the date of this filing, Southern has not issued any of the Common authorized to be sold. The Order authorized Southern to adjust the number of shares of Common to be issued and sold to reflect the effects of any subsequent stock splits. Southern now proposes to extend until September 30, 2004 the time in which it may issue and sell up to 25 million shares of Common, as provided in the Order. Some or all of the Common may be issued and sold through a primary shelf registration program in accordance with rule 415 under the Securities Act of 1933, as amended, or otherwise to, or through, one or more underwrites or dealers for resale in one or more public offerings, or to investors directly or through agents.

Southern proposes to use the proceeds from the sale of the Common to make additional investments in exempt wholesale generators and foreign utility companies, as those terms are defined in sections 32 and 33 of the Act, and in its other subsidiary companies to the extent provided in separate proceedings.

For the Commission by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–30194 Filed 11–18–99; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–42138; File No. SR–CTA/CQ–99–02]

Consolidated Tape Association; Order Granting Approval of Fifth Charges Amendment to the Second Restatement of the Consolidated Tape Association Plan and the Fourth Charges Amendment to the Restated Consolidated Quotation Plan

November 15, 1999.

I. Introduction

On August 2, 1999, the Consolidated Tape Association (''CTA'') and the Consolidated Quotation (''CQ'') Plan Participants (''Participants'')[1] filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') amendments to the Restated CTA Plan and CQ Plan pursuant to Section 11A(a)(3) of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 11Aa3–2 thereunder.[3] Notice of the proposed plan amendments appeared in the **Federal Register** on August 30, 1999.[4] The Commission received two comment letters in response to the proposals.[5]

[1] The amendments were executed by each Participant in each of the Plans. The participants include American Stock Exchange LLC (''Amex''), Boston Stock Exchange, Inc., Chicago Board Options Exchange, Inc., Chicago Stock Exchange, Inc., Cincinnati Stock Exchange, Inc., National Association of Securities Dealers, Inc., New York Stock Exchange, Inc. (''NYSE''), Pacific Exchange, Inc., and Philadelphia Stock Exchange, Inc.

[2] 15 U.S.C. 78k–1(a)(3).

[3] 17 CFR 240.11Aa3–2.

[4] Securities Exchange Act Rel. No. 41767 (August 19, 1999), 64 FR 47204.

[5] *See* letters from Gene L. Finn, Finn Associates, Inc., received September 23, 1999 (''Finn Letter'') and Sam Scott Miller, Orrick, Herrington & Sutcliffe LLP, to Jonathan G. Katz, Secretary, Commission, dated September 7, 1999 (''Schwab Letter No. 1''). In this letter, Schwab requests that the Commission incorporate by reference comments it submitted concerning network A's proposed reduction in fees. *See* letter from Sam Scott Miller, Orrick, Herrington & Sutcliffe, LLP, to Jonathan G. Katz, Secretary, Commission, dated July 26, 1999 (''Schwab Letter No. 2'').

This order approves the proposed plan amendments.

II. Description of the Proposal

A. Nonprofessional Subscriber Service Rates

The participants under the Plans that make network B last sale information and Network B quotation information available (the ''Network B Participants'') currently impose on vendors a monthly fee of $3.25 for each nonprofessional subscriber to whom the vendor provides a Network B market data display service. These amendments propose to reduce that monthly fee from $3.25 to $1.00 for each nonprofessional subscriber to whom a vendor provides a Network B display service during the month.

For the nonprofessional subscriber rates (rather than the much higher professional subscriber rates) to apply to an of its subscribers, a vendor must make certain that the subscriber qualifies as a nonprofessional subscriber,[6] subject to the same criteria that have applied since 1985, when the network B Participants first established a reduced rate for nonprofessional subscribers. Only those nonprofessional subscribers that actually gain access to at least one real-time Network B quote or price during the month will be charged the proposed fees by the Network B Participants.

B. Pay-for-Use-Rates

Since February 1997, the Network B Participants have conducted a pilot program pursuant to which vendors, providing Network B market data display services to nonprofessional subscribers, have been afforded the following tiered usage schedule as an alternative to the flat $3.25 monthly rate the Network B Participants have historically imposed on nonprofessional subscribers.

1–50 quotes=$0.50 per month, per quote
51–250 quotes=$3.25 per month, per user
251+quotes=$35.00 per month, per user

Based on their experience with the tiered usage schedule and their extensive consultation with vendors and member organizations, the Network B Participants are proposing to alter the tiered usage schedule and to make the altered fee structure part of the Network B rate schedule.

Under the altered rates, each vendor would pay:

i. Three-quarter of one cent ($0.0075) per quote packet[7] for each of the first 20 million quote packets that it distributes during a month;

ii. one-half of one cent ($0.005) per quote packet for each of the next 20 million quote packets that it distributes during that month (*i.e.*, quote packets 20,000,001 through 40,000,000 million); and

iii. one-quarter of one cent ($0.0025) for every quote packet in excess of 40 million that it distributes during that month.

C. Interplay of Nonprofessional-Subscriber and Pay-for-Use Rates

The Network B Participants further propose to reduce the cost exposure of vendors and broker-dealers by permitting them to limit the amount due from each nonprofessional subscriber each month. The vendors and broker-dealers would be eligible to pay the lower of either (i) the aggregate pay-per-use fees that would apply to the subscriber's usage during the month or (ii) the flat monthly $1.00 nonprofessional subscriber fee. The Network B Participants propose to offer this flexibility to each subscriber that qualifies as a nonprofessional subscriber and that has agreed to the terms and conditions that apply to the receipt of market information as a nonprofessional subscriber.

For ease of administration, the Network B Participants propose to allow each vendor and broker-dealer to apply the $1.00 fee for any month in which each nonprofessional subscriber retrievers 134 or more quote packets during the month, without regard to the marginal per-quote rate that the vendor or broker-dealer pays that month (*i.e.*, three-quarters, one-half or one-quarter cent per quote packet). In addition, each vendor may reassess each month to determine which fee is more economical, the per-quote fee or the nonprofessional subscriber fee.

III. Summary of Comments

The Commission received two comment letters concerning the proposed amendments to the CTA and CQ Plans.[8] One comment contends that because the nonprofessional fees are ''per se'' discriminatory, the Commission should abrogate them.[9] Finn also believes that ''without audited incremental cost information, the reasonableness of specific fees cannot be determined.''[10] Moreover, without proper documentation to support the implementation of these fees, Finn believes the proposal is inconsistent with the Act's standards of fairness and competition.[11] Furthermore, Finn suggests that all SRO fee structures be reviewed to determine the feasibility of establishing a universal rate for access to all market data.[12]

The other commenter, however, supported approval of the proposed fee reductions, but also asserted that other aspects of the proposal were not consistent with the statutory standards applicable to market information fees and should be abrogated.[13] Schwab stated that, although the fee reductions benefit retail investors, the CTA's overall fee structure is not fair and reasonable because the fees charged are unrelated to the actual costs of providing the market information.[14] Moreover, Schwab notes that the reduced costs of collecting and disseminating market information have resulted from an increase in dissemination of market information through electronic means. According to Schwab, because the new fee structure does not reflect these reduced costs, the fee structure does not comply with the standards of Section 11A of the Act.[15]

Schwab believes that the tiered fee structure improperly discriminates among broker-dealers and vendors based on the number of subscribers they have and their subscribers' use of market data.[16] However, it suggests that a lower-level fee of $.50 is a more appropriate level for the monthly unlimited-use fee and should be applied [to] all subscribers.[17] Schwab also believes that the enterprise cap included in the Network A proposal could be similarly implemented in the context of this proposal.[18] While Schwab believed the cap for Network A was excessive, it

[6] A ''nonprofessional subscriber'' shall receive the information solely for his personal, non-business use. The subscriber shall not furnish the information to any other person. *See* NYSE and the Amex Application and Agreement for the Privilege of Receiving Last Sale Information & Bond Last Sale Information as a Nonprofessional Subscriber, for the qualifications necessary to be classified as a nonprofessional subscriber.

[7] A ''quote packet'' refers to any data element, or all data elements, relating to a single issue. Last sale price, opening price, high price, low price, volume, net change, bid, offer, size, best bid and best offer all exemplify data elements. ''IBM'' exemplifies a single issue. An index value constitutes a single issue data element.

[8] *See* note 5 *supra.*

[9] Finn Letter at 2–3.

[10] *Id.* at 6.

[11] *Id.* at 2.

[12] *Id.* at 5.

[13] Schwab Letter No. 2 at 6–7.

[14] *Id.* at 4.

[15] *Id.* at 5–6.

[16] Schwab Letter No. 2 at 3.

[17] Schwab Letter No. 1 at 2. *See also* Securities Exchange Act Rel. No. 41977 (Oct. 5, 1999), 64 FR 55503 (Oct. 13, 1999), where the monthly fee for each nonprofessional subscriber was reduced to $1.00 for each of the first 250,000 nonprofessional subscribers who received Network A market data and $.50 for each additional subscriber.

[18] *Id.*

noted a cost-based cap may be the most equitable means for assessing fees and reducing the costs of market data users.[19]

IV. Discussion

The Commission finds that the proposed plan amendments are consistent with the Act and the rules and regulations thereunder.[20] Specifically, the Commission finds that approval of the amendments is consistent with Rule 11Aa3–2(c)(2)[21] of the Act.

The Commission currently is conducting a broad review of the fee structures for obtaining market information and of the role of market information revenues in funding the self-regulatory organizations. As part of its review, the Commission intends to issue a release describing existing market information fees and revenues and inviting public comment on the subject. The proposed rule change implicates many of the issues that the Commission is reviewing. These include identifying the appropriate standards for determining (1) whether the fees charged by an exclusive processor of market information are fair and reasonable, and (2) whether a fee structure is unreasonably discriminatory or an inappropriate burden on competition.

The Commission has decided to approve the proposed plan amendments pending its review because they represent, in part, a very substantial reduction in the market information fees applicable to retail investors. In particular, the monthly fee for non-professional subscribers would be reduced from $3.25 per month to no greater than $1.00 per month. Under this monthly fee structure, there would be no limit on the amount of market information that retail investors would be entitled to receive. Such, a fee structure may enable vendors, to provide retail investors with more useful services than have previously been provided. In this regard, the proposed plan amendments are consistent with, and significantly further, one of the principal objectives for the national market system set forth in Section 11A(a)(1)(C)(iii)—increasing the availability of market information to broker-dealers and investors. The Commission wishes to emphasize, however, that its review of market information fees and revenues is ongoing and may require a re-evaluation of the fee structures contained in the proposed plan amendments at some point in the future.

The Commission recognizes that one commenter opposes the proposal, while the other supports approval of the proposed fee reductions primarily because they represent an improvement over the CTA's current fee structure. Other issues raised by the commenters (*e.g.*, discriminatory impact of the CTA fee structure on on-line investors, the appropriate standard to be applied in assessing the fairness and reasonableness of market information fees) have broader implications on the functioning and regulation of the national market system. As such, these issues will be addressed in the Commission's forthcoming concept release on market information fees and revenues.

The Commission also finds that the minor, non-substantive changes made to the form of Schedules A–3 of Exhibit E to both the CTA and CQ Plans reflect the proposed amendments, thereby clarifying the fee schedules to make them more understandable.

V. Conclusion

It is therefore ordered, pursuant to Section 11A of the Act,[22] and the rules thereunder, that the proposed amendments to the Plans (SR–CTA/CQ–99–02) are approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[23]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–30274 Filed 11–18–99; 8:45 am]

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[19] *Id.*

[20] The Commission has considered the proposed amendments' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f). The Commission realizes that the modified fee structure, as applied, may create competitive disparties. The new fee structure will, however, reduce the cost of access to market information, which should result in a reduction of costs for investors. The competitive concerns and solutions suggested by the commenters will be addressed in the Commission's forthcoming concept release on market information fees and revenues.

[21] 17 CFR 240.11Aa3–2(c)(2).

[22] 15 U.S.C. 78k–1.

[23] 17 CFR 200.30–3(a)(27).

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–24135; File No. 812–11480]

PFL Life Insurance Company, et al.

November 15, 1999.

AGENCY: Securities and Exchange Commission (''SEC'' or ''Commission'').

ACTION: Notice of application for an order under the Investment Company Act of 1940 (the ''Act'').

Applicants: PFL Life Insurance Company (''PFL''), PFL Endeavor VA Separate Account (''PFL Endeavor Account''), PFL Endeavor Target Account, PFL Retirement Builder Variable Annuity Account (''Retirement Builder Account''), PFL Life Variable Annuity Account C (''PFL Account C''), AUSA Life Insurance Company (''AUSA''), AUSA Endeavor Variable Annuity Account (''AUSA Endeavor Account''), AUSA Endeavor Target Account (together with PFL Endeavor Target Account, the ''Target Accounts''), AFSG Securities Corporation (''AFSG''), Western Reserve Life Assurance Co. Of Ohio (''Western Reserve''), WRL Series Annuity Account (''WRL Account''), Peoples Benefit Life Insurance Company (''Peoples Benefit''), Peoples Benefit Life Insurance Company Separate Account V (''People's Benefit Account''), Transamerica Occidental Life Insurance Company (''Transamerica Occidental''), Separate Account VA–2L, Transamerica Life Insurance Company of New York (''Transamerica New York''), Separate Account VA–2LNY, Separate Account VA–6NY, Transamerica Life Insurance and Annuity Company (''Transamerica''), Separate Account VA–6, and Separate Account VA–7 (all collectively, the ''Applicants'').

Relevant Sections of the Act: Order of exemption requested under Section 6(c) of the Act from the Sections 2(a)(32), 22(c), and 27(i)(2)(A) of the Act and Rule 22c–1 thereunder.

Summary of Application: PFL, AUSA, Western Reserve, Peoples Benefit, Transamerica Occidental, Transamerica New York, and Transamerica are together referenced herein as the ''Companies,'' or individually as a ''Company.'' The PFL Endeavor Account, Retirement Builder Account, PFL Account C, AUSA Endeavor Account, Target Accounts, WRL Account, Peoples Benefit Account, Separate Account VA–2L, Separate Account VA–2LNY, Separate Account VA–6NY, Separate Account VA–6, and Separate Account VA–7 are together referenced herein as the ''Accounts,'' or individually as an ''Account.'' Applicants seek an order of the Commission exempting them with respect to the support of variable annuity policies that are similar in all material respects to the policies described herein, issued both currently (''Policies'') and the future (''Future Policies of Accounts''), and any other separate accounts of the Companies or their affiliated insurance companies that are controlling, controlled by, or under common control (within the meaning of Section 2(a)(9) of the Act) with the Companies (''Future Accounts'') that

support in the future variable annuity policies that are similar in all material respects to the policies described herein (''Future Policies of Future Accounts,'' and together with the Future Policies of Accounts, ''Future Policies''), and certain National Association of Securities Dealers, Inc. (''NASD'') member broker-dealers which may, in the future, act as principal underwriter of such policies (''Future Underwriters''), from the provisions of Sections 2(a)(32), 22(c), and 27(i)(2)(A) of the Act and Rule 22c–1 thereunder, pursuant to Section 6(c) of the Act, to the extent necessary to permit the deduction of a charge on certain redemptions under the optional Family Income Protector Rider, as summarized herein, available to the Policies and Future Policies.

Filing Date: The Application was filed on January 27, 1999, and amended and restated on June 3, 1999, July 12, 1999, and November 2, 1999.

Hearing Or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the Commission and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 8, 1999, and should be accompanied by proof of service on Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary of the Commission.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549–0609. Applicants, c/o Frank A. Camp, Esquire, PFL Life Insurance Company, 4333 Edgewood Road, NE, Cedar Rapids, Iowa 52499. Copies to Frederick R. Bellamy, Esquire, Sutherland Asbill & Brennan LLP, 1275 Pennsylvania Avenue, N.W., Washington, D.C. 20004–2415.

FOR FURTHER INFORMATION CONTACT: Ann L. Vlcek, Senior Counsel, or Susan M. Olson, Branch Chief, Office of Insurance Products, Division of Investment Management, at (202) 942–0670.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the Public Reference Branch of the SEC, 450 Fifth Street, N.W., Washington, D.C. 20549–0102 (tel. (202) 942–8090).

Applicant's Representations

1. PFL is a stock life insurance company. It was incorporated under the name NN Investors Life Insurance Company, Inc. under the laws of the State of Iowa on April 19, 1961. It is principally engaged in the sale of life insurance and annuity policies, and is licensed in the District of Columbia, Guam, and in all states except New York. PFL is a wholly-owned indirect subsidiary of AEGON USA, Inc., which conducts substantially all of its operations through subsidiary companies engaged in the insurance business or in providing non-insurance financial services. All of the stock of AEGON USA, Inc. is indirectly owned by AEGON n.v. of the Netherlands. AEGON n.v., a holding company, conducts its business through subsidiary companies engaged primarily in the insurance business.

2. AUSA is a stock life insurance company. It was incorporated under the laws of the State of New York on October 3, 1947. It is principally engaged in the sale of life insurance and annuity policies, and is licensed in the District of Columbia, and in all states except Alabama and Hawaii. AUSA is a wholly-owned indirect subsidiary of AEGON USA, Inc.

3. Western Reserve was incorporated under the laws of Ohio on October 1, 1957. It is engaged in the business of writing life insurance policies and annuity contracts. Western Reserve is licensed in the District of Columbia, Guam, Puerto Rico, and in all states except New York. Western Reserve is wholly-owned by First AUSA Life Insurance Company, a stock life insurance company which is wholly-owned by AEGON USA, Inc.

4. Peoples Benefit is a stock life insurance company incorporated under the laws of Missouri on August 6, 1920. People Benefit is principally engaged in offering life insurance, annuity contracts, and accident and health insurance, and is admitted to do business in all states except New York, as well as the District of Columbia and Puerto Rico. Peoples Benefit is a wholly-owned indirect subsidiary of AEGON USA, Inc.

5. Transamerica Occidental is a stock life insurance company incorporated under the laws of the State of California on June 30, 1906. It is mainly engaged in the sale of life insurance and annuity contracts. On July 21, 1999, Transamerica Corporation completed its merger with a subsidiary of AEGON N.V. Transamerica Corporation, a subsidiary of AEGON N.V., indirectly owns Transamerica Occidental.

6. Transamerica New York is a stock life insurance company incorporated under the laws of the State of New York on February 5, 1986. It is mainly engaged in the sale of life insurance and annuity policies. On July 21, 1999, Transamerica Corporation completed its merger with a subsidiary of AEGON N.V. Transamerica Corporation, a subsidiary of AEGON N.V., indirectly owns Transamerica New York.

7. Transamerica is a stock life insurance company incorporated under the laws of the State of California in 1966. The company moved to North Carolina in 1994. It is principally engaged in the sale of life insurance and annuity policies. On July 21, 1999, Transamerica Corporation completed its merger with a subsidiary of AEGON N.V. Transamerica Corporation, a subsidiary of AEGON N.V., indirectly owns Transamerica.

8. Each Account is comprised of sub-accounts established to receive and invest net purchase payments under the Policies (the ''Subaccounts''). The income, gains and losses, realized or unrealized, from the assets allocated to each Subaccount (each ''Investment Option'') will be credited to or charged against that Investment Option without regard to other income, gains or losses of the Companies. Applicants represent that each Account meets the definition of a ''separate account'' in Rule 0–1(e) under the Act.

9. The Board of Directors of PFL established the PFL Endeavor Account on January 19, 1990. The PFL Endeavor Account is registered under the Act as a unit investment trust (File No. 811–6032). The assets of the PFL Endeavor Account support certain flexible premium variable annuity policies, and interests in the PFL Endeavor Account offered through such contracts have been registered under the Securities Act of 1933 (''1933 Act'') on Form N–4 (File Nos. 33–33085 and 33–56908).

10. The Board of Directors of AUSA established the AUSA Endeavor Account on September 7, 1994. The AUSA Endeavor Account is registered under the Act as a unit investment trust (File No. 811–8750). The assets of the AUSA Endeavor Account support certain flexible premium variable annuity policies, and interests in the AUSA Endeavor Account offered through such contracts have been registered under the 1933 Act on Form N–4 (File No. 33–83560).

11. The Board of Directors of PFL established the Retirement Builder Account on March 29, 1996. The Retirement Builder Account is registered under the Act as a unit investment trust (File No. 811–7689).

The assets of the PFL Endeavor Account support certain flexible premium variable annuity policies, and interests in the PFL Endeavor Account offered through such contracts have been registered under the 1933 Act on Form N–4 (File No. 33–7509).

12. The Board of Directors of PFL established PFL Account C on February 20, 1997. PFL Account C is registered under the Act as a unit investment trust (File No. 811–9503). The assets of PFL Account C support certain flexible premium variable annuity policies, and interests in PFL Account C offered through such contracts have been registered under the 1933 Act on Form N–4 (File No. 33–83957).

13. The Target Accounts are registered under the Act as open-end management investment companies (File No. 811–8377 for the PFL Endeavor Target Account, and File No. 811–9305 for the AUSA Endeavor Target Account). The assets of the Target Accounts support certain flexible premium variable annuity policies, and interests in the Target Accounts offered through such contracts have been registered under the 1933 Act on Form N–3 (File Nos. 33–47027 and 33–36297 for contracts issued by PFL, and File No. 33–76803 for contracts issued by AUSA). Each Target Account is a managed account and may be divided into two or more Subaccounts, each of which invests according to specific investment strategies. PFL may establish additional Subaccounts in the future.

14. The Board of Directors of Western Reserve established the WRL Account on April 12, 1988. The WRL Account is registered under the Act as a unit investment trust (File No. 811–5672). The assets of the WRL Account support certain flexible premium variable annuity policies, and interests in the WRL Account offered through such contracts have been registered under the 1933 Act on Form N–4 (File Nos. 33–82705 and 33–84773).

15. The Board of Directors of Peoples Benefit established the Peoples Benefit Account on February 14, 1992. The Peoples Benefit Account is registered under the Act as a unit investment trust (File No. 811–06564). The assets of the Peoples Benefit Account support certain flexible premium variable annuity policies, and interests in the Peoples Benefit Account offered through such contracts have been registered under the 1933 Act on Form N–4 (File No. 33–79502).

16. The Board of Directors of Transamerica Occidental established Separate Account VA–2L on May 22, 1992. Separate Account VA–2L is registered under the Act as a unit investment trust (File No. 811–07042). The assets of Separate Account VA–2L support certain flexible premium variable annuity policies, and interests in Separate Account VA–2L offered through such contracts have been registered under the 1933 Act on Form N–4 (File No. 33–49998).

17. The Board of Directors of Transamerica New York established Separate Account VA–2LNY on June 23, 1992. Separate Account VA–2LNY is registered under the Act as a unit investment trust (File No. 811–07368). The assets of Separate Account VA–2LNY support certain flexible premium variable annuity policies, and interests in Separate Account VA–2LNY offered through such contracts have been registered under the 1933 Act on Form N–4 (File No. 33–55152).

18. The Board of Directors of Transamerica New York established Separate Account VA–6NY on September 11, 1996. Separate Account VA–6NY is registered under the Act as a unit investment trust (File No. 811–08677). The assets of Separate Account VA–6NY support certain flexible premium variable annuity policies, and interests in Separate Account VA–6NY offered through such contracts have been registered under the 1933 Act on Form N–4 (File No. 33–47219).

19. The Board of Directors of Transamerica established Separate Account VA–6 on June 11, 1996. Separate Account VA–6 is registered under the Act as a unit investment trust (File No. 811–07753). The assets of Separate Account VA–6 support certain flexible premium variable annuity policies, and interests in Separate Account VA–6 offered through such contracts have been registered under the 1933 Act on Form N–4 (File Nos. 33–09745 and 33–37883).

20. The Board of Directors of Transamerica established Separate Account VA–7 on June 11, 1996. Separate Account VA–7 is registered under the Act as a unit investment trust (File No. 811–08835). The assets of Separate Account VA–7 support certain flexible premium variable annuity policies, and interests in Separate Account VA–7 offered through such contracts have been registered under the 1933 Act on Form N–4 (File No. 33–57697).

21. AFSG, an affiliate of the Companies, is the principal underwriter and the distributor of the Policies. AFSG is registered with the Commission as a broker-dealer under the Securities Exchange Act of 1934, as amended, and is a member of the NASD. AFSG may enter into written sales agreements with various broker-dealers or banks to aid in the distribution of the Policies.

22. Each Investment Option (other than the Target Accounts) will invest exclusively in a designated series of shares, representing an interest in a particular portfolio of one or more designated management investment companies of the series type (''Funds''). Applicants reserve the right to designate the shares of another portfolio of the Funds or of other management investment companies of the series type (''Other Funds'') as the exclusive investment vehicle for each new Investment Option that may be created in the future. Subject to Commission approval under Section 26(b) of the Act, Applicants also reserve the right to substitute the shares of another portfolio of the Funds or of other Funds for the portfolio previously designated as the exclusive investment vehicle for each Investment Option.

23. The Policies are flexible premium variable annuity policies issued by the Companies through their respective separate accounts. The Policies provide for accumulation of values on a variable basis, fixed basis, or both during the accumulation period, and may provide settlement or annuity payment options on a variable basis, fixed basis, or both. The Policies may be purchased on a non-qualified tax basis. The Policies may also be purchased and used in connection with plans qualifying for favorable federal income tax treatment.[1]

24. The Policy owner determines how the initial net purchase payment will be allocated among the Investment Options of the Accounts and any guaranteed period options or dollar cost averaging option of the fixed account (the ''Fixed Account Options''). The Policy owner may allocate any whole percentage of net purchase payments, from 0% to 100%, to each Investment Option and to each Fixed Account Option. The Policy value will vary with the investment performance of the Investment Options selected, and the Policy owner bears the entire risk for amounts allocated to an Account.

25. A Policy owner may transfer Policy values. Transfers out of a Subaccount generally must be for at least a specified dollar amount, or the entire value of the Subaccount. If less than the specified amount would remain in a Subaccount following such

[1] The Companies state that the policies may use different terminology, such as contract or policy, investment option or investment division or sub-account, fixed account or guaranteed period option or general account, annuity commencement date or annuity date or maturity date, funds or portfolios, policy value or cash value or cash value or account value, *etc.*

a transfer, a Company may, at its discretion, either deny the transfer or include that amount as part of the transfer. Transfers may be limited, or a charge may apply. The Policy owner may surrender the Policy or make a partial withdrawal from the Policy value.

26. The Policy owner may elect or change an annuity payment option during the life-time of the Policy owner. The first annuity payment will be made as of the annuity commencement date. The Policy owner generally may change the annuity commencement date, subject to limits specified in the prospectus. The amount of each annuity payment under the annuity payment options will depend on the sex (if allowed) and age of the annuitant (or annuitants) at the time the first payment is due and the payment option.

27. The Family Income Protector rider [2] is an optional benefit which is available to Policy owners in the Accounts. It assures a Policy owner a minimum level of income in the future by guaranteeing a minimum annuitization value after 10 years, based on the Policy value at the date the rider is issued (the ''Rider Date'') [3] (adjusted for any withdrawals, applicable taxes and charges), and increased by a guaranteed annual growth rate (the ''Minimum Annuitization Value''). On the Rider Date, the Minimum Annuitization Value equals the Policy value. Thereafter, it will equal the Policy value on the Rider Date, plus any additional payments, minus an adjustment for any withdrawals made after the Rider Date, accumulated at an annual growth rate (specified in the rider) minus premium taxes. The annual growth rate is currently 6% per year, but may be increased or decreased by a Company at its discretion. The annual growth rate will never be less than 3% per year and, once in effect with respect to a particular rider, cannot be changed from the rate specified in that rider. A Policy owner may upgrade a Minimum Annuitization Value within thirty days after a Policy anniversary if the Policy value is greater than the Minimum Annuitization Value. If a Policy owner elects such an upgrade, a Company will terminate the Family Income Protector Rider then in effect and issue a new Family Income Protector Rider.

28. A Policy owner may only exercise the Family Income Protector within the thirty days immediately following the tenth or later Policy anniversary after the Family Income Protector is elected. If an upgrade is elected, the earliest date that a Policy owner may exercise the Family Income Protector will be extended to the tenth Policy anniversary following the upgrade. If a Policy owner annuities their Policy at any other time, the Family Income Protector cannot be exercised, and therefore will provide no benefits. The Family Income Protector is only applicable if a Policy owner annuitizes under the rider.

29. The Companies guarantee that the annuity payments under the Family Income Protector Rider will never be less than the initial payment, and will also be ''stabilized'' or held constant during each Policy year. Under the Family Income Protector Rider, each Policy year the ''stabilized'' payments are guaranteed to never be less than the initial payment for the Policy year. However, if the annuity units in the selected Subaccounts can support a payment higher than the initial payment, then the ''stabilized'' payment will be that higher amount. For this ''stabilized'' payment guarantee, the Companies currently deduct a ''stabilized payment'' fee equal to an effective annual rate of 1.25% of the daily net asset value in the variable investment options. This stabilized payment fee is deducted only after annuitization, and only if annuitization is under the Family Income Protector Rider. This fee is reflected in the daily calculation of annuity unit values.[4] The Companies state that this stabilized payment fee is not the subject of this application.

30. Prior to the annuity commencement date, there will be a charge made each year for expenses related to the Family Income Protector available under the terms of the Family Income Protector Rider. The Companies deduct this charge through the cancellation of accumulation units at each Policy anniversary and at surrender to compensate it for the increased risks associated with providing the Family Income Protector Rider. The Companies state that the Family Income Protector Rider charge is not deducted when the Policy owner makes a partial withdrawal. Upon a full surrender prior to annuitization, the full charge is deducted. Surrenders are not permitted after annuitization, since the Family Income Protector Rider only applies to life contigent payment options. The Family Income Rider charge does not apply after annuitization. It is appropriate to deduct the charge upon surrender because it is an annual charge, and absent a surrender it applies retroactively, i.e., at the end of each Policy year. Deferring the charge and deducting it retroactively, at the end of each year, instead of deducting it prospectively, at the beginning of each year, gives Policy owners the benefit of any investment gains on that amount during the year.

31. The current Family Income Protector Rider charge equals an annual rate of 0.30% of the Minimum Annuitization Value on the previous Policy anniversary. The Companies guarantee that this charge will never exceed an annual rate of 0.50% of the Minimum Annuitization Value. The Family Income Protector Rider charge for a particular Rider cannot be changed after its Rider Date. Once elected, the Family Income Protector Rider cannot be canceled. This fee is the subject of this application.

Applicants' Legal Analysis

1. Applicants respectfully request that the Commission, pursuant to Section 6(c) of the Act, grant the exemptions set forth below to permit the Applicants to assess the full Family Income Protector Rider charge upon surrender where the Policy owner has elected the Family Income Protector Rider.

2. Section 6(c) authorizes the Commission, by order upon application, to conditionally or unconditionally grant an exemption from any provision, rule or regulation of the Act to the extent that the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that, because the provisions described below may be inconsistent with certain aspects of the Family Income Protector Rider charge, they are seeking exemptions from Section 2(a)(32), 27(i)(2)(a) and 22(c) of the Act, and Rule 22c–1 thereunder, pursuant to Section 6(c), to the extent necessary to assess the full Family Income Protector Rider charge against Policies when a Policy owner surrenders the Policy prior to annuitization. Applicants seek exemptions therefrom in order to avoid any questions concerning the Policies' compliance with the Act and rules thereunder. For the reasons discussed below, Applicants assert that the

[2] The Companies state that the ''Family Income Protector'' is the name of the benefit in the current PFL and AUSA Policies, and that the benefit may have a different name in the other Companies' Policies (or in Future Policies). The Companies also state that, in the future, this feature may be included in the base policy rather than as a rider or endorsement.

[3] The Companies state that the Rider Date can be the date the policy is issued or a later date when the rider is elected.

[4] The Companies state that a Company may charge up to 2.25% for this stabilized payment fee but, for a particular rider, the amount cannot change after the Rider Date.

deduction of the Family Income Protector Rider charge is in the public interest and consistent with the protection of investors and purposes fairly intended by the Act.

3. Rule 6c–8(b) under the Act exempts a registered separate account and its depositor or principal underwriter from certain provisions of the Act and Rule 22c–1 to permit imposition of a deferred sales load on variable annuity contracts participating in such separate account. Applicants maintain that Rule 6c–8(b) is not available with respect to imposition of the Family Income Protector Rider charge because it is a charge for an optional insurance benefit rather than a deferred sales load.

4. Rule 6c–8(c) provides exemptions from certain provisions of the Act and Rule 22c–1 to permit deduction of a full annual administrative services fee from variable annuity contacts upon surrender. Applications state that the Family Income Protector Rider charge, however, is not a fee for ''administrative services,'' and therefore Rule 6c–8(c) is not applicable. Applicants note, however, that Rule 6c–8(c) permits deduction of the entire annual administrative fee upon surrender; it does not require that the feel be prorated.

5. Section 2(a)(32) of the Act defines ''redeemable security'' as any security under the terms of which the holder, upon its presentation to the issuer, is entitled to receive approximately his proportionate share of the issuer's current net assets, or the cash equivalent thereof. Applicants submit that the imposition of a Family Income Protector Rider charge upon surrender does not violate Section 2(a)(32) of the Act. Applicants state that the Companies assess the Family Income Protector Rider charge to compensate them for the increased risk they bear if a Policy owner elects the Family Income Protector Rider. Applicants further maintain that the Family Income Protector benefit represents an optional insurance benefit that the Companies may provide through the life of the Policy and for which they are entitled to receive compensation. Applicants state that, normally, the Family Income Protector Rider charge accrues each Policy year and is deducted retroactively on each Policy anniversary, for that prior Policy year. Applicants submit that, by deducting the Family Income Protector Rider charge upon a Policy owner's surrender, the Policy owner merely compensates a Company for the additional risk a Company bears. Applicants state that, accordingly, the deduction of the Family Income Protector Rider charge upon surrender is a legitimate charge for an optional insurance benefit and, therefore, does into reduce the amount of each Account's current net assets a Policy owner would otherwise be entitled to receive.

6. Section 22(c) of the Act gives the Commission authority to make rules and regulations applicable to registered investment companies and to principal underwriters of, and dealers in, the redeemable securities of any registered investment company. Rule 22c–1, promulgated under Section 22(c) of the Act, in pertinent part, prohibits a registered investment company issuing a redeemable security, a person designated in such issuer's prospectus as authorized to consummate transactions in such security, and a principal underwriter of, or dealer in, any such security from selling, redeeming, or repurchasing any such security except at a price based on the current net asset value of such security. Applicants represent that, although they assess the Family Income Protector Rider charge upon surrender, the net surrender value is still determined based on the current net asset value. Applicants state that the Companies deduct the Family Income Protector Rider charge from the surrender proceeds. Applicants maintain that, accordingly the assessment of the Family Income Protector Rider charge upon surrender, or at any other time during the life of the Policy, will not alter the Policy's current accumulation unit value.

7. Applicants contend that the deduction of the Family Income Protector Rider charge is consistent with the policy behind Rule 22c–1. Applicants note that the Commission's stated purpose in adopting Rule 22c–1 was to minimize (1) dilution of the interests of other security holders and (2) speculative trading practices that are unfair to such holders. Applicants maintain that the Family Income Protector Rider charge will in no way have the dilutive effect that Rule 22c–1 is designed to prohibit, because a surrendering Policy will ''receive'' no more than an amount equal to the Policy value determined pursuant to the formula set out in the Policy after the receipt of the Policy owner's request for surrender of the Policy. Furthermore, Applicants state that variable annuities, by nature, do not lend themselves to the kind of speculative short-term trading that Rule 22c–1 was aimed against and, even if they could be so used, the Family Income Protector Rider charge would discourage, rather than encourage, any such trading.

8. Section 27(i)(2)(A) of the Act, in pertinent part, makes it unlawful for any registered separate account funding variable insurance contracts, or for the sponsoring insurance company of such account, to sell any such contract unless such contract is a redeemable security. Applicants submit that the assessment of a Family Income Protector Rider charge upon a Policy owner's surrender, which is fully disclosed in the prospectus for the Policy (or a supplement thereto), should not be construed as a restriction on redemption. Applicants maintain that the Policies are redeemable securities and that the imposition of the Family Income Protector Rider charge upon surrender represents nothing more than the deduction of an insurance charge that could otherwise be deducted daily through the life of the Policy (or prospectively, at the beginning of each year, rather than retrospectively). Moreover, as they previously stated, Applicants note that the charge is only assessed if the Policy owner has elected the optional Family Income Protector Rider.

9. Accordingly, Applicants request exemptions from Sections 2(a)(32), 22(c), and 27(i)(2)(A) of the Act and Rule 22c–1 thereunder, to the extent necessary to permit the deduction upon surrender of the full non pro rata Family Income Protector Rider charge, currently equal to 0.30% (but in no event more than 0.50%) of the Minimum Annuitization Value as described herein. For the reasons set forth above, Applicants believe that the exemptions requested are necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act and Commission precedent.

10. Applicants seek relief not only for themselves with respect to the support of the Policies, but also with respect to Future Accounts and Future Policies as described herein.

11. Applicants represent that the terms of the relief requested with respect to any Policies or Future Policies funded by the Accounts and Future Accounts are consistent with the standards set forth in section 6(c) of the Act and Commission precedent.

12. Applicants represent that the terms of the relief requested with respect to any Future Underwriters are also consistent with the standards set forth in section 6(c) of the Act and Commission precedent.

13. Applicants state that, without the requested class relief, exemptive relief for any Future Account, Future Policy or Future Underwriter would have to be

requested and obtained separately. Applicants represent that these additional requests for exemptive relief would present no issues under the Act not already addressed herein. Applicants state that, if the Applicants were to repeatedly seek exemptive relief with respect to the same issues addressed herein, investors would not receive additional protection or benefit, and investors and the Applicants could be disadvantaged by increased costs from preparing such additional requests for relief. Applicants argue that the requested class relief is appropriate in the public interest because the relief will promote competitiveness in the variable annuity market by eliminating the need for the Companies or their affiliates to file redundant exemptive applications, thereby reducing administrative expenses and maximizing efficient use of resources. Elimination of the delay and the expense of repeatedly seeking exemptive relief would, Applicants opine, enhance each Applicant's ability to effectively take advantage of business opportunities as such opportunities arise. Applicants submit, for all the reasons stated herein, that their request for class exemptions is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act, and that an order of the Commission including such class relief, should, therefore, be granted. All entities that currently intend to rely on the requested order are named as Applicants. Any entity that relies upon the requested order in the future will comply with the terms and conditions contained in this application.

Conclusion

Applicants represent that the Family Income Protector Rider charge under the Policies meets (and the charge under Future Policies will meet) all of the requirements for exemptive relief pursuant to Section 6(c) of the Act. Applicants submit that the requested exemptions are necessary and appropriate in the public interest and consistent with protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants therefore request that an order be granted permitting the proposed transactions.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–30272 Filed 11–18–99; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 24132; 812–11772]

STI Classic Funds and SunTrust Banks, Inc.; Notice of Application

November 15, 1999.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 17(b) of the Investment Company Act of 1940 (the ''Act'') for an exemption from section 17(a) of the Act.

SUMMARY OF THE APPLICATION: Applicants request an order to permit two series of a registered open-end management investment company to acquire all of the assets, subject to certain liabilities, of two other series of the investment company. Because of certain affiliations, applicants may not rely on rule 17a–8 under the Act.

APPLICANTS: STI Classic Funds (''STI Funds'') and SunTrust Banks, Inc. (''SunTrust'').

FILING DATES: The application was filed on September 13, 1999. Applicants have agreed to file an amendment to the application during the notice period, the substance of which is reflected in this notice.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 8, 1999, and should be accompanied by proof of service on applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Commission, 450 Fifth Street, N.W., Washington, D.C. 20549–0609. Applicants, c/o W. John McGuire, Esq., Morgan, Lewis & Bockius LLP, 1800 M Street, N.W., Washington, D.C. 20036–5869.

FOR FURTHER INFORMATION CONTACT: Emerson S. Davis, Sr., Senior Counsel, at (202) 942–0714, or George J. Zornada, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the Commission's Public Reference Branch, 450 Fifth Street, N.W., Washington, D.C. 20549–0102 (telephone (202) 942–8090).

Applicants' Representations

1. STI Funds, a Massachusetts business trust, is registered under the Act as an open-end management investment company and offers thirty-six series, including the SmallCap Growth Stock Fund (''Small Cap Fund'') and the International Equity Fund (''International Fund'') (together, the ''Acquiring Funds'') and the Sun Belt Equity Fund (''Equity Fund'') and the Emerging Markets Equity Fund (''Emerging Markets Fund'') (together, the ''Acquired Funds,'' and together with the Acquiring Funds, the ''Funds'').

2. SunTrust, a Georgia corporation, is a bank holding company and the parent of Trusco Capital Management, Inc. (''Trusco'') and STI Capital Management, N.A. (''STI Capital''), both wholly-owned subsidiaries. Trusco is registered under the Investment Advisers Act of 1940 (the ''Advisers Act'') and is the investment adviser to the Small Cap and Equity Funds. STI Capital, a bank, is exempt from registration under the Advisers Act and is the investment adviser to the International and Emerging Markets Funds. Currently, bank subsidiaries of SunTrust own in the aggregate, in a fiduciary capacity, 25% or more of the outstanding voting securities of each Fund.

3. On May 18, 1999 and August 17, 1999, the board of trustees of STI Funds (the ''Board''), including all of the trustees who are not ''interested persons,'' as defined in section 2(a)(19) of the Act (''Independent Trustees''), approved a plan of reorganization between the Small Cap Fund and Equity Fund and between the International Fund and Emerging Markets Fund, respectively (the ''Plan''). Under the Plan, on the date of the exchange (the ''Closing Date''), which is currently anticipated to be December 13, 1999, each Acquiring Fund will acquire all of the assets and certain stated liabilities of

the corresponding Acquired Fund in exchange for shares of the Acquiring Fund having an aggregate net asset value equal to the aggregate net asset value of the Acquired Fund's shares determined as of the close of business on the business day immediately preceding the Closing Date. As soon as reasonably practical after the Closing Date, each Acquired Fund will liquidate and distribute *pro rata* the shares of the Acquiring Fund to the shareholders of the Acquired Fund (''Reorganization''). The net asset value of the assets received will be determined in the manner set forth in each Fund's current prospectus and statement of additional information.

4. Applicants state that the investment objectives, policies and restrictions of each Acquired Fund are substantially similar to those of its corresponding Acquiring Fund. Each Fund offers Trust Shares which are not subject to any sales charge or rule 12b–1 distribution fee. Both the Equity and Small Cap Funds offer (a) Investor Shares, which are subject to a front-end sales load and rule 12b–1 distribution fee and (b) Flex Shares, which are subject to a contingent deferred sales charge (''CDSC'') and rule 12b–1 distribution fee.[1] Shareholders of Trust, Investor and/or Flex Shares of each Acquired Fund will receive corresponding shares of each Acquiring Fund. The holding period used to determine whether a CDSC will apply to a holder of Flex Shares of the Small Cap Fund who becomes a shareholder as a result of the Reorganization will include any period of time that the shareholder held shares of the Equity Fund. No sales charges will be imposed in connection with the Reorganization. Any expenses incurred in connection with the Reorganization will be borne by SunTrust.

5. The Board, including all of the Independent Trustees, determined that the Reorganization is in the best interests of the shareholders of each Fund, and that the interests of the existing shareholders of each Fund would not be diluted as a result of the Reorganization. In assessing the Reorganization, the Board considered various factors, including: (a) the compatibility of the investment objectives, policies and limitations of the Acquired and corresponding Acquiring Funds; (b) the expense ratios of the Acquired and Acquiring Funds (c) the terms and conditions of the Reorganization; (d) the tax-free nature of the Reorganization; and (e) the potential economics of scale to be gained from the Reorganization.

6. The Reorganization is subject to a number of conditions precedent, including that: (a) the shareholders of each Acquired Fund will have approved the Plan; (b) STI Funds will have received an opinion of counsel that the Reorganization will be tax-free for the Funds; and (c) applicants will receive from the Commission an exemption from section 17(a) of the Act for the Reorganization. The Plan may be terminated and the Reorganization abandoned at any time prior to the Closing Date by the Board or any authorized officer of STI Funds if it is determined that circumstances have changed to make the Reorganization inadvisable. Applicants agree not to make any material changes to the Plan without prior Commission approval.

7. Definitive proxy materials have been filed with the Commission and were mailed to shareholders of the Acquired Funds on or about November 10, 1999. A special meeting of shareholders of the Acquired Funds is scheduled for December 10, 1999.

Applicants' Legal Analysis

1. Section 17(a) of the Act, in relevant part, prohibits an affiliated person of a registered investment company, or an affiliated person of such a person, acting as principal, from selling any security to, or purchasing any security from, the company. Section 2(a)(3) of the Act defines an ''affiliated person'' of another person to include (a) any person directly or indirectly owning, controlling, or holding with power to vote 5% or more of the outstanding voting securities of the other person; (b) any person 5% or more of whose securities are directly or indirectly owned, controlled, or held with power to vote by the other person; (c) any person directly or indirectly controlling, controlled by, or under common control with the other person; and (d) if the other person is an investment company, any investment adviser of that company.

2. Rule 17a–8 under the Act exempts certain mergers, consolidations, and sales of substantially all of the assets of registered investment companies that are affiliated persons, or affiliated persons of an affiliated person, solely by reason of having a common investment adviser, common directors, and/or common officers, provided that certain conditions set forth in the rule are satisfied. Applicants believe that rule 17a–8 may not be available in connection with the Reorganization because the Funds may be deemed to be affiliated by reasons other than having a common investment adviser, common directors, and/or common officers. Applicants state that subsidiary banks of SunTrust own in the aggregate, as a fiduciary, 25% or more of the outstanding voting securities of each Fund and that SunTrust therefore may be deemed to be an affiliated person of the Funds, resulting in the Acquired Funds being affiliated persons of an affiliated person of the Acquiring Funds. Applicants also state that the Funds, by virtue of the above ownership, may be deemed to be under common control and therefore affiliated persons of each other.

3. Section 17(b) of the Act provides, in relevant part, that the Commission may exempt a transaction from the provisions of section 17(a) if evidence establishes that the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and that the proposed transaction is consistent with the policy of each registered investment company concerned and with the general purposes of the Act.

4. Applicants request an order under section 17(b) of the Act exempting them from section 17(a) to the extent necessary to complete the Reorganization. Applicants submit that the Reorganization satisfies the standards of section 17(b) of the Act. Applicants believe that the terms of the Reorganization are reasonable and fair and do not involve overreaching. Applicants state that the investment objectives and policies of each Acquired Fund are substantially similar to those of its corresponding Acquiring Fund. Applicants also state that the Board, including all of the Independent Trustees, has made the requisite determinations that the participation of the Acquired and Acquiring Funds in the Reorganization is in the best interests of each Fund and that such participation will not dilute the interests of the existing shareholders of each Fund. In addition, applicants state that the Reorganization will be on the basis of relative net asset value.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–30273 Filed 11–18–99; 8:45 am]

BILLING CODE 8010–01–M

[1] The Equity Fund and Small Cap Fund Investor Shares have the same front-end sales load. Investor Shares of the Equity Fund have a distribution fee of .43% and Investor Shares of the Small Cap Funds have a distribution fee of .50%. Flex Shares have the same maximum distribution fees.

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: [64 FR 61957, November 15, 1999]

STATUS: Closed Meeting.

PLACE: 450 Fifth Street, N.W., Washington, D.C.

DATE PREVIOUSLY ANNOUNCED: November 9, 1999.

CHANGE IN THE MEETING: Time Change.

The closed meeting scheduled for Tuesday, November 16, 1999 at 1:30 p.m., has been changed to Tuesday, November 16, 1999, at 2:30 pm.,

Commissioner Hunt, as duty officer, determined that Commission business required the above change and that no earlier notice thereof was possible.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 942–7070.

Dated: November 16, 1999.

Jonathan G. Katz,

Secretary.

[FR Doc. 99–30315 Filed 11–16–99; 4:27 pm]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Small Business Administration's intentions to request approval on a new, and/or currently approved information collection.

DATES: Submit comments on or before January 18, 2000.

ADDRESSES: Send all comments regarding whether this information collection is necessary for the proper performance of the function of the agency, whether the burden estimate is accurate, and if there are ways to minimize the estimated burden and enhance the quality of the collections, to James Rivera, Supervisory Loan Specialist, Office of Disaster Assistance, Small Business Administration, 409 3rd Street, SW, Suite 6050.

FOR FURTHER INFORMATION CONTACT: James Rivera, Supervisory Loan Specialist, 202–205–7562 or Curtis B. Rich, Management Analyst, 202–205–7030.

SUPPLEMENTARY INFORMATION:

Title: ''Military Reservist Economic Injury Disaster Loan Application''.

Form No: 5R.

Description of Respondents: Small Businesses applying for economic injury Loan assistance as a result of an essential employee Being called up for active duty.

Annual Responses: 2,500.

Annual Burden: 5,000.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 99–30215 Filed 11–18–99; 8:45 am]

BILLING CODE 8025–01–P

OFFICE OF SPECIAL COUNSEL

Privacy Act of 1974, System of Records

AGENCY: Office of special Counsel.

ACTION: Notice of administrative changes in System of Records and Proposed Revision of Routine Uses.

SUMMARY: Pursuant to the Privacy Act of 1974, as amended (5 U.S.C. 552a), and 5 U.S.C. 553, the Office of Special Counsel (OSC) previously published notices in the **Federal Register** describing the system of records maintained in connection with OSC program responsibilities. The notice at 52 FR 29907 (1987) proposed the amendment of routine uses and identified specific exemptions from the act; the notice at 58 FR 62394 (1993) designated the system as ''OSC/GOVT–1, OSC Complaint, Litigation and Political Activity Files,'' among other administrative changes. Pursuant to 5 U.S.C. 552a(e)(4) and (11), the OSC is revising the system notice for OSC/GOVT–1 to update information about individuals covered by the system, records in the system, authority for maintenance of the system, the system manager, retrievability of records, access controls, and records source categories; update legal citations; and make technical corrections. The OSC also proposes to revise the system notice by amending the description of two current routine uses, and by adding a new routine use.

SUPPLEMENTARY INFORMATION: The OSC is an independent investigative and prosecutorial agency, authorized to investigate allegations of: (a) Prohibited personnel practices under 5 U.S.C. 2302(b), as well as certain other matters listed at 5 U.S.C. 1216; (b) prohibited political activity under 5 U.S.C. 7321–7326 by federal and District of Columbia employees, and prohibited political activity under 5 U.S.C. 1501–1508 by certain state and local government employees; (c) violations by federal agencies of certain employment and reemployment rights referred by the U.S. Department of Labor under 38 U.S.C. 4324; and (d) prohibited personnel practices referred by the Merit Systems Protection Board (MSPB) under 5 U.S.C. 1221(f)(3). The OSC is further authorized to seek appropriate corrective and/or disciplinary action in these matters through litigation before the MSPB. Also, under 5 U.S.C. 1213, the OSC operates a hotline channel through which current and former federal employees or employees or former federal employees can make confidential whistleblower disclosures.

Information developed in connection with these OSC program responsibilities is maintained in the OSC/GOVT–1 system of records, which includes certain records subject to the Privacy Act. These include records in complaint files, generally retrieved by the name of the person filing an allegation of a prohibited personnel practice, improper political activity, or other prohibited activity; records in disclosure files, generally retrieved by the name of a person filing an allegation through the OSC whistleblower disclosure channel; records in disciplinary action litigation files, generally retrieved by the name of the person charged by the OSC in litigation before the MSPB; and records in defensive litigation files, generally retrieved by the name of the plaintiff in the action.

The OSC is revising the OSC/GOVT–1 system of records to: (1) Update descriptions of individuals covered by the system, records in the system (including addition of specific reference to records maintained in connection with statutory referrals from the Labor Department under 38 U.S.C. 4324, the MSPB, and requests and decisions under the Freedom of Information and privacy Acts), authority for maintenance of the system, system manager, retrievability of records, access controls, and records source categories; (2) update legal citations shown in prior **Federal Register** notices, and (3) make other technical corrections.

The OSC also proposes to revise routine uses of information in the system of records by: (1) amending the description of current routine uses ''m'' and ''n'' (to conform them more closely to the guidance issued by the Office of Management from which they were derived, most notably by clarifying that disclosures may also be made in connection with litigation in which the OSC has an interest, after the required

determination described in the current routine uses); and (2) adding a new routine use, at ''q'' (allowing disclosures of information to the news media and the public in specified circumstances, except to the extent that the Special Counsel determines that disclosure of specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy).

COMMENTS: Interested persons may submit comments in writing to the OSC on the proposed revisions and additions of routine uses shown in this notice. Comments should be sent to Marion S. Berman Bowytz, Planning and Advice Division, U.S. Office of Special Counsel, 1730 M Street, NW, Suite 300, Washington DC 20036–4505. The revised and new routine uses will become effective 30 days after publication of this notice, unless comments received by the OSC before then warrant further changes.

FOR FURTHER INFORMATION CONTACT: Marion S. Berman Bowytz, U.S. Office of Special Counsel, at (202) 653–8971.

OSC/GOVT–1

SYSTEM NAME:

OSC/GOVT–1, OSC Complaint, Litigation and Political Activity Files.

SYSTEM LOCATION:

Management Division, U.S. Office of Special Counsel, 1730 M Street, NW., Suite 200, Washington, DC 20036–4505.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The principal categories of individuals covered by the system are persons filing allegations of prohibited personnel practices, improper political activity, or other alleged prohibited activities; persons identified as engaging or participating in such practices of activities; persons filing disclosures of alleged wrongdoing by federal agencies, and persons identified as engaging or participating in such wrongdoing; persons charged by the OSC in disciplinary action complaints filed by the OSC with the Merit systems Protection Board (MSPB); and plaintiffs seeking remedies against the OSC in litigation related to the performance of its official functions.

CATEGORIES OF RECORDS IN THE SYSTEM:

Correspondence with persons (or their representatives) filing allegations of prohibited personnel practices, improper political activity, or other prohibited activities; correspondence with other agencies, entities, or individuals referring matters to the OSC for review and/or investigation; exhibits and other documentation from complainants, governmental entities or other third parties; interview records, including notes, summaries, or transcripts; affidavits; reports or other summaries of investigation; factual and legal summaries and analyses; administrative determinations; referrals to other agencies for appropriate action; records created or compiled in connection with litigation by or against the OSC, or pertinent to OSC operations; requests and decisions under the Freedom of Information and/or Privacy Acts; and other correspondence and documents arising out of the performance of official OSC functions under 5 U.S.C. 1211–1221, 1501–1508, and 7321–7326; 38 U.S.C. 4324, and other applicable law or regulation.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552, 552a, 1211–1221, 1501–1508, and 7321–7326; and 38 U.S.C. 4324.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. To disclose the fact that an allegation of prohibited personnel practices or other prohibited activity has been filed;

b. To disclose information to the Office of Personnel Management (OPM) pursuant to Civil Service Rule 5.4 (5 CFR 5.4), or to obtain an advisory opinion concerning the application or effect of civil service laws, rules, regulations or OPM guidelines in particular situations;

c. To disclose to the Equal Employment Opportunity Commission or any other agency or office concerned with the enforcement of the antidiscrimination laws, information concerning any allegation or complaint of discrimination based on race, color, religion, sex, national origin, age, or handicapping condition;

d. To disclose information to the MSPB or the President upon the filing or referral of a disciplinary action complaint against an employee on the basis of an OSC investigation;

e. To disclose information to an agency, the MSPB, OPM, and the President reporting, under 5 U.S.C. 1214, the results of investigations which disclose reasonable grounds to believe a prohibited personnel practice has occurred, exists, or is to be taken;

f. To disclose information to Congress in connection with the submission of an annual report on activities of the Special Counsel;

g. To disclose information to any agency or person regarding allegations of prohibited personnel practices or other prohibited activity or prohibited political activity filed against an agency or any employee thereof, for the purposes of conducting an investigation, in transmitting information to an agency under 5 U.S.C. 1213(c)(1) and the OSC procedures established thereunder; or to give notice of the status or outcome of the investigation;

h. To disclose information to any source from which additional information is requested (to the extent necessary to identify the individual, inform the source of the purpose(s) of the request, and to identify the type of information requested), where necessary to obtain information relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the conducting of a security or suitability investigation of an individual, the letting of a contract, or the issuance of a license, grant, or other benefit; To disclose information to the Office of Management and Budget (OMB) at any stage in the legislative coordination and clearance process in connection with private relief legislation, as set forth in OMB Circular No. A–19;

j. To provide information to a congressional office from the record of an individual in response to an inquiry from that congressional office (made at the request of that individual);

k. To furnish information to the National Archives and Records Administration (NARA) in records management inspections conducted under authority of 44 U.S.C. 2904 and 2906;

l. To produce summary descriptive statistics and analytical studies in support of the function for which the records are collected and maintained or for related work force studies;

m. To disclose records to the Department of Justice (DOJ) when:

(1) The OSC, or

(2) Any employee of the OSC in his or her official capacity, or

(3) Any employee of the OSC in his or her individual capacity where the DOJ has agreed to represent the employee, or

(4) The United States, where the OSC determines that litigation is likely to affect the OSC,

is a party to litigation or has an interest in such litigation, and the use of such records by the DOJ is deemed by the OSC to be relevant and necessary to the litigation, provided, however, that the OSC determines that disclosure of the records to the DOJ is a use of the information contained in the records that is compatible with the purpose of which the records were collected;

n. To disclose records maintained by the OSC in a proceeding before a court or adjudicative body before which the OSC is authorized to appear, when:

(1) The OSC, or

(2) Any employee of the OSC in his or her official capacity,

(3) Any employee of the OSC in his or her individual capacity where the OSC has agreed to represent the employee, or

(4) The United States, where the OSC determines that litigation is likely to affect the OSC,

is a party to litigation or has an interest in such litigation, and the OSC determines that use of such records is relevant and necessary to the litigation, provided, however, that the OSC determines that disclosure of the records is a use of the information contained in the records that is compatible with the purpose for which the records were collected;

o. To disclose information to the MSPB to aid in the conduct of special studies by the Board use 5 U.S.C. 1204(a)(3);

p. To disclose information to the Office of Inspector General (OIG) or comparable internal inspection, audit, or oversight office of an agency for the purpose of facilitating the coordination and conduct of investigations and review of allegations within the purview of both the OSC and the agency OIG or comparable office; and

q. To disclose information to the news media and the public when (1) the matter under investigation has become public knowledge, (2) the Special Counsel determines that disclosure is necessary to preserve confidence in the integrity of the OSC investigative process or is necessary to demonstrate the accountability of OSC officers, employees, or individuals covered by this system, or (3) the Special Counsel determines that there exists a legitimate public interest (*e.g.*, to demonstrate that the law is being enforced, or to deter the commission of prohibited personnel practices, prohibited political activity, and other prohibited activity within the OSC's jurisdiction), except to the extent that the Special Counsel determines in any of these situations that disclosure of specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

POLICIES AND PRACTICES FOR STORAGE, RETRIEVAL, ACCESS CONTROLS, RETENTION AND DISPOSAL OF RECORDS IN THE SYSTEM:

STORAGE:

These records are stored in a variety of media, primarily consisting of file folders, and computer storage equipment.

RETRIEVABILITY:

Files in this system of records are retrievable by the names of key individuals or agencies involved (e.g., complainants or requesters; subjects identified in corrective action or disciplinary proceedings, warning letters, or other determinations; legal, congressional, or other representatives or points of contact; key witnesses), although files are generally retrieved by the name of: (a) The complainant alleging a prohibited personnel practice, improper political activity, or other activity; (b) the person filing an allegation through the OSC whistleblower disclosure channel; (c) the person filing an allegation of prohibited political activity; (d) the person charged by the OSC in litigation before the MSPB; and (e) the plaintiff in litigation against the OSC.

SAFEGUARDS:

These records are located in lockable metal file cabinets or in secured areas, with access limited to those personnel whose official duties require access.

RETENTION AND DISPOSAL:

NARA keeps records about prohibited personnel practices and other prohibited activity for three years after the matter or case is closed, or for six years if the file has been the subject of a Freedom of Information Act request. NARA is responsible for disposal of agency records pursuant to law and regulation.

SYSTEM MANAGER(S) AND ADDRESS:

Records Management Officer, U.S. Office of Special Counsel, 1730 M Street, NW, Suite 216, Washington, DC 20036–4505.

NOTIFICATION PROCEDURE:

Individuals who wish to inquire whether this system contains information about them should contact the system manager. To assist in the process of locating and identifying records, individuals should furnish the following:

a. Name and address;

b. Date and place of birth;

c. Social Security number;

d. A description of the circumstances under which records may have been included in the system.

RECORD ACCESS PROCEDURES:

Same as notification procedure, above.

CONTESTING RECORD PROCEDURES:

Individuals who wish to contest records about them should contact the system manager, identify any information they believe should be corrected, and furnish a statement of the basis for the requested correction along with all available supporting documents and materials.

RECORD SOURCE CATEGORIES:

Information in this system of records is obtained from a variety of sources, consisting of complainants or others on whose behalf allegations, or requests for information, have been submitted or referred to the OSC; legal, congressional, or other representatives or points of contact; other government bodies; witnesses and subjects in matters under review; principals involved in litigation matters, including parties and their representatives; and other persons or entities furnishing information pertinent to the discharge of functions for which the OSC is responsible.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

a. Complaint, Litigation and Political Activity files containing investigatory material compiled by the OSC for law enforcement purposes are exempt to the extent allowed under subsections (k)(2) and (5) of the Privacy Act. This exemption is necessary to protect confidential sources and facilitate the voluntary cooperation of witnesses during inquiries into allegations of prohibited personnel practices or other prohibited activities.

b. Testing or examination material compiled by the OSC solely to determine individual qualifications for appointment or promotion in the Federal service is exempt to the extent allowed under subsection (k)(6) of the Privacy Act. This exemption is necessary to prevent the disclosure of information that would potentially give an individual an unfair competitive advantage or diminish the utility of established examination procedures.

c. The OSC reserves the right to assert exemptions for records received from another agency that could be properly claimed by that agency in responding to a request, and the OSC may refuse access to information compiled in reasonable anticipation of a civil action or proceeding, pursuant to subsection (d)(5) of the Privacy Act.

Dated: November 2, 1999.

Elaine Kaplan,

Special Counsel.

[FR Doc. 99–30180 Filed 11–18–99; 8:45 am]

BILLING CODE 7405–01–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD01–99–190]

Lottery for Spectator Craft Viewing Anchorages for OPSAIL 2000/ International Naval Review 2000 (INR 2000), Port of New York/New Jersey

AGENCY: Coast Guard, DOT.

ACTION: Notice. Request for applications.

SUMMARY: Coast Guard Activities New York seeks applications from owner/operators of vessels greater than 25 meters (82 feet) in length who desire to participate in a lottery for an anchorage permit in Upper New York Bay during OPSAIL 2000/INR 2000 activities between June 29, 2000, and July 5, 2000. This action is necessary for the Captain of the Port New York to manage the number of vessels that will be authorized to anchor in the temporary anchorages established for this event and to make those selections with an equitable methodology. This action is intended to reduce the risk of vessel collisions due to the expected large number of vessels anchored in close proximity. To be considered, all applications must include the vessel type, name, length, beam, draft, air draft, vessel identification number or state registration number, mailing address and phone number. Provide electronic mail address and facsimile number if available. There will be two separate drawings held based on vessel length.

The first drawing will be for vessels greater than 60 meters (197 feet). Vessels chosen will be required to be in their designated position by 2 a.m. on July 4, 2000, and must remain in position for the entire OPSAIL 2000/INR 2000 event. These vessels will only be permitted to depart when authorized by the Captain of the Port and should plan on remaining in position until 6 a.m. on July 5, 2000. Vessels may also be required to have assist vessel(s) in attendance as determined by the Captain of the Port New York. The second drawing will be for vessels between 25 meters (82 feet) and 60 meters (197 feet). These vessels will be required to be in position by 7 a.m. July 4, 2000. The Captain of the Port New York will assign as many anchorage permits as is deemed safe due to the expected large amount of vessel traffic in the Port of New York/New Jersey during OPSAIL 2000/INR 2000.

Applications must be submitted to the Waterways Oversight Branch at the address under **ADDRESSES.** Persons wanting acknowledgement of receipt of their application should enclose a stamped, self-addressed postcard or envelope. Vessels that are randomly chosen to receive an anchorage permit will be notified within 7 calendar days of the drawing. The specific anchorage location for each vessel will be provided at a later date. Depending on the number of applications received, selection of lottery winners will either be by hand-drawing or randomly selected by computer program. Applications must be sent on an 8½ × 11 inch or size A–4, white sheet of paper. Early submission will not increase the chance of being selected and only one submission per vessel will be entered into the lottery.

DATES: Applications for vessels greater than 60 meters (197 feet) in length must reach the Coast Guard on or before January 5, 2000. Applications for vessels between 25 meters (82 feet) and 60 meters (197 feet) in length must reach the Coast Guard on or before February 1, 2000.

ADDRESSES: Applications may be mailed to the Waterways Oversight Branch, Coast Guard Activities New York, 212 Coast Guard Drive, Staten Island, New York 10305, or deliver them to room 205 at the same address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant J. Lopez, Waterways Oversight Branch, Coast Guard Activities New York (718) 354–4193, facsimile (718) 354–4190.

Dated: November 9, 1999.

R.E. Bennis,

Captain, U.S. Coast Guard, Captain of the Port, New York.

[FR Doc. 99–30269 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 29797]

FAA Order 1050.1E; Environmental Impacts: Policies and Procedures; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Correction.

SUMMARY: The Federal Aviation Administration (FAA) issued a notice and request for public comment on a FAA proposal to revise its procedures for implementing the National Environmental Policy Act. The notice along with a draft of the procedures document (draft FAA Order 1050.1E) were published in the **Federal Register** (64 FR 55526; October 13, 1999). As published, the draft Order 1050.1E contains a few errors that are in need of clarification. The following corrections are made to draft Order 1050.1E:

On page 55527 at the bottom of the second column and the top of the third column, delete the text string ''Medium Approach Lighting System with a REIL (MALSR/SALSR)'' and substitute the following in lieu thereof; ''Medium Intensity Approach Lighting System with Runway Alignment Indicator Light System (MALSR); Simplified Shortened Approach Lighting System with Runway Alignment Indicator Light System (SSALSR);''.

On page 55529, Table of Contents, change the paragraph heading of paragraph 7 to read ''More Detailed Guidance;'' change the paragraph heading of paragraph 206 to read ''Special Instructions;'' and change the Appendix 2 heading from ''[Reserved]'' to ''Policies and Procedures for Air Traffic Environmental Actions.''

On page 55544, in item no. 2 under the heading Equipment and Instrumentation Actions, delete the text string ''Medium Approach Lighting System with a REIL (MALSR/SALSR)'' and substitute the following in lieu thereof; ''Medium Intensity Approach Lighting System with Runway Alignment Indicator Light System (MALSR); Simplified Shortened Approach Lighting System with Runway Alignment Indicator Light System (SSALSR);''.

On page 55545, under item no. 19, in both sentences; replace the word ''TACAN'' with the text ''Ultra-High Frequency Tactical Air Navigation Aid''.

On page 55594, first column under the heading ''Appendix 2,'' add a new appendix title ''Policies and Procedures for Air Traffic Environmental Actions'' prior to the text ''[Reserved]''.

On page 55594, under ''Appendix 3. Airports Environmental Handbook 5050.4A,'' delete the text ''5050.4A'' from the Appendix 3 heading; and delete the last sentence of paragraph 1.

Draft Order 1050.1E may be accessed at internet address: http://www.aee.faa.gov/aee-200/10501e.htm

Dated: November 10, 1999.

Paul R. Dykeman,

Deputy Director of Environment and Energy.

[FR Doc. 99–30266 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Proposed Issuance of Policy Memorandum 99–XX, Issuance of an Experimental Airworthiness Certificate for Show Compliance Flight Testing or Research and Development

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of availability.

SUMMARY: After reviewing a 1995 guidance memorandum, it has been noted that changes are needed to better ensure compliance with Title 14 Code of Federal Regulations and Title 49 of the United States Code. This notice announces the availability of proposed Policy Memorandum (PM) 99–XX for review and comment. The purpose of this memorandum is to address the issuance of an experimental airworthiness certificate to perform each flight test required for the purpose of showing compliance to the airworthiness regulations or for research and development. To add clarification, the PM also defines the differences in a show compliance flight test versus an operational flight check after installation of an FAA-approved modification or alteration, and emphasizes showing compliance through analysis and/or ground testing when appropriate.

DATES: Comments submitted must be received no later than January 18, 2000.

ADDRESSES: Copies of proposed PM 99–XX can be obtained from and comments may be returned to the following: Federal Aviation Administration, Production and Airworthiness Certification Division, AIR–200, Room 815, 800 Independence Avenue, SW., Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Loyal Woodworth, Federal Aviation Administration, Production and Airworthiness Certification Division, AIR–200, Room 815, 800 Independence Avenue, SW., Washington, DC 20591, (202) 267–8361. E-mail address: loyal.woodworth@faa.gov.

SUPPLEMENTARY INFORMATION: Interested persons are invited to comment on the proposed PM 99–XX listed in this notice, by submitting such written data, views, or arguments as they desire to the aforementioned address. Comments must be marked ''Comments to PM 99–XX.'' The Director, Aircraft Certification Service, will consider all communications received on or before the closing date, before issuing the final PM. Comments received on the proposed PM 99–XX may be examined before and after the comment closing date in Room 815, FAA headquarter building (FOB–10A), 800 Independence Avenue, SW., Washington, DC 20591, between 8:30 a.m. and 4:30 p.m.

Section 21.181(a)(1) of Title 14 of the CFR states that a standard airworthiness certificate remains effective as long as maintenance, preventive maintenance, and alterations are performed in accordance with 14 CFR parts 4 and 91. Section 91.407(a)(1) states that an aircraft that has undergone maintenance, preventive maintenance, rebuilding, or alteration may not be operated unless it has been approved for return to service by a person authorized under 14 CFR 43.7, and the maintenance record entry required by §§ 43.9 or 43.11 has been made. The impact of the above regulations is that a standard airworthiness certificate for an aircraft that has undergone alteration is not effective until the aircraft is returned to service in accordance with part 43. Operation of that aircraft prior to return to service would violate 14 CFR 91.203(a)(1) and 49 U.S.C. 44.711(a)(1), because there would not be an effective airworthiness certificate for the aircraft.

Part 21 of Title 14 contains the requirements for amending type certificates and for issuing supplemental type certificates. A type certificate (TC) may be amended (ATC) for the purpose for incorporating a major change into the type design; a supplemental type certificate (STC) is issued for a major change to type design made by someone other than the TC holder (although nothing prohibits the TC holder from obtaining an STC). In order to issue an ATC or STC, the FAA must find that the altered product complies with the airworthiness standards incorporated in the TC.

In many instances, a flight test of the altered aircraft is required in order to show compliance with the applicable airworthiness requirements; some regulations specifically require flight testing. A major alteration must be performed in accordance with FAA-approved data (*see, e.g.,* 14 CFR §§ 65.95(a)(1), 121.379(b), 135.437(b), and 145.51), and a successful flight test, if required, is necessary for the FAA to approve the data. Because the flight test is performed after the alterations are made to the aircraft, but before the aircraft is returned to service, there is no effective airworthiness certificate for the aircraft unless the FAA issues an experimental airworthiness certificate. The FAA issues that experimental certificate under 14 CFR § 21.191(b), Experimental certificates for showing compliance with regulations.

In addition, an aircraft may be altered for the purpose of conducting research and development. For the purpose of conducting that kind of flight before returning the aircraft to service in its unaltered state, the FAA will issue an experimental certificate under 14 CFR § 21.191(a), Experimental certificates for research and development. Similarly, aircraft may be flown after a major alteration or major repair is made to it, but before the aircraft is returned to service; in that case, and experimental airworthiness certificate or another special airworthiness certificate is issued.

The 1995 guidance memorandum, No. 95–4, Issuance of Experimental Certificates for Flight test of Modified Aircraft, dated March 7, 1995, improperly described situations where an aircraft with a major alteration ''could'' be operated ''under'' its standard airworthiness certificate before it was returned to service. That part of the memorandum was contrary to the regulatory and statutory requirements described above. Proposed Policy Memorandum No. 99–XX would cancel 95–4, and would provide correct guidance to FAA field offices that deal offices that deal with applications for ATCs and STCs.

Part of the confusion created by 95–4 was because it did not adequately explain the difference between the above-described flight test for showing compliance with regulations, and the ''operational flight check'' required by 14 CFR § 91.407(b). Section 91.407(b) states (in pertinent part):

> No person may carry any person (other than crewmembers) in an aircraft that has been * * * altered in a manner that may have appreciably changed its flight characteristics or substantially affected its operation in flight until an appropriately rated pilot with at least a private pilot certificate flies the aircraft, makes an operational check of the * * * alternation made, and logs the flight in the aircraft records.

(In addition, paragraph (c) of § 91.407 provides an exception to paragraph (b), where ground tests and/or inspections show conclusively that the alteration has not appreciably changed the flight characteristics or substantially affected the flight operation of the aircraft.)

As noted above, paragraph (a) of § 91.407 prohibits all persons from operating an altered aircraft prior to return to service; in contrast, paragraph (b) addresses operation of the aircraft with passengers aboard. Thus, paragraph (b) of § 91.407 is premised on the operator of the aircraft complying

with paragraph (a), and the flight check required by paragraph (b) is conducted after the aircraft is returned to service. After the aircraft is returned to service, the standard airworthiness certificate is effective, and there is no need for an experimental airworthiness certificate to be issued for the operational flight check.

Issued in Washington, DC, on November 15, 1999.

Frank P. Paskiewicz,

Manager, Production and Airworthiness Certification Division, AIR–200.

[FR Doc. 99–30267 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–98–4370]

Transportation Equity Act for the 21st Century (TEA–21); Implementation of the Transportation and Community and System Preservation Pilot Program

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice; request for applications for Fiscal Year (FY) 2001 Transportation and Community and System Preservation grants; request for FY 2001 TCSP research proposals; request for comments on program implementation and research needs.

SUMMARY: This document provides guidance on section 1221 of the Transportation Equity Act for the 21st Century (TEA–21), which established the Transportation and Community and System Preservation Pilot (TCSP) Program. The TCSP provides funding for grants and research to investigate and address the relationship between transportation and community and system preservation. The States, local governments, metropolitan planning organizations (MPOs), tribal governments, and other local and regional public agencies are eligible for discretionary grants to plan and implement transportation strategies which improve the efficiency of the transportation system, reduce environmental impacts of transportation, reduce the need for costly future public infrastructure investments, ensure efficient access to jobs, services and centers of trade, and examine development patterns and identify strategies to encourage private sector development patterns which achieve these goals. FY 2001 is the third year of the TCSP program.

The FHWA seeks requests for FY 2001 TCSP grants, recommendations for FY 2001 TCSP research, and public comments from all interested parties regarding implementation of the TCSP program and research related to the program in FY 2001 and beyond.

DATES: Applications for FY 2001 grants should be received in the appropriate FHWA Division Office by January 31, 2000. Recommendations for FY 2001 TCSP research activities also should be received in the FHWA's Office of Planning and Environment by January 31, 2000. Comments on program implementation, research needs, and priorities should be received by the DOT Docket Clerk on or before January 31, 2000.

ADDRESSES: Grant requests should be submitted to the FHWA's Division Office in the State of the applicant. Division addresses and telephone numbers are provided in an attachment to this notice. Research recommendations should be submitted to the Office of Human Environment, Planning and Environment, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590.

Your signed, written comments on program implementation should refer to the docket number appearing at the top of this notice and you should submit the comments to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. All comments received will be available for examination at the above address between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments should include a self-addressed, stamped envelope or postcard.

FOR FURTHER INFORMATION CONTACT: Ms. Susan B. Petty, Office of Human Environment, Planning and Environment, (HEPH), (202) 366–0106; or Mr. S. Reid Alsop, Office of the Chief Counsel, (HCC–31), (202) 366–1371, Federal Highway Administration, 400 Seventh Street SW., Washington D.C. 20590. Office hours are from 8:00 a.m. to 5:00 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

All comments received by the U.S. DOT Dockets, Room PL–401, are available through the Docket Management System internet web site at: *http://dms.dot.gov*.

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the Office of the Federal Register's home page at: *http://www.nara.gov/fedreg* and the Government Printing Office's database at: *http://www.access.gpo.gov/nara*. Information is also available on the FHWA Web page at: *http://www.fhwa.dot.gov/programs.html* or the TCSP web site at: *http://tcsp-fhwa.volpe.dot.gov/*.

Background

Section 1221 of the TEA–21 (Public Law 105–178, 112 Stat. 107 (1998)) established the TCSP. The Department of Transportation's Strategic Plan (1997–2003) includes a series of goals related to safety, mobility and access, economic growth and trade, enhancement of communities and the natural environment, and national security. The TCSP pilot program furthers each of these goals and provides funding for grants and research to investigate and address the relationship between transportation and community and system preservation. By funding innovative activities at the neighborhood, local, metropolitan, regional, and State levels, the program is intended to increase the knowledge of the costs and benefits of different approaches to integrating transportation investments, community preservation, land development patterns, and environmental protection. It will enable communities to investigate and address important relationships among these many factors.

The TCSP program offers the States, local governments, MPOs, tribal governments, and other public agencies the opportunity to develop, implement and evaluate current preservation practices and activities that support these practices, as well as to develop new and innovative approaches to meet the purposes of the TCSP grant program (see Section II). Funding for the TCSP was authorized at $25 million per year for FY's 2000 through 2003 by TEA–21. The Administration's FY 2000 budget proposed increased funding for TCSP to $50 million as part of the President's Livability Initiative. Under the Department of Transportation and Related Appropriations Act, FY 2000, (Public Law 106–69, 113 Stat. 986 (1999)), the Congress authorized $25 million for 39 special projects and provided an additional $10 million to the TCSP to fund FY 2000 applications. The FHWA received 292 grant proposals for FY 2000 which are being reviewed. FY 2000 awards are planned to be made in December 1999.

This notice includes three sections: Section I—TCSP Program Information;

Section II—Requests for FY 2001 TCSP Grants; and Section III—Recommendations for FY 2001 TCSP Research.

Section I: TCSP Program Information

Introduction

The TCSP provides funding for grants and research to investigate and address the relationship between transportation and community and system preservation. States, local governments, tribal governments, and MPOs are eligible for discretionary grants to plan and implement strategies which improve the efficiency of the transportation system, reduce environmental impacts of transportation, reduce the need for costly future public infrastructure investments, ensure efficient access to jobs, services and centers of trade, and examine development patterns and identify strategies to encourage private sector development patterns which achieve these goals. Through the TCSP, States, local governments, and MPOs implement and evaluate current preservation practices and activities that support these practices, as well as develop new and innovative approaches. FY 2001 is the third year of the TCSP program.

The TCSP supports the Administration's high priority goals to encourage the development of livable communities. Within the context of livable communities, reduction of greenhouse gas emissions in the transportation sector is one focus for the TCSP.

Purposes

Section 1221 of TEA–21 identifies five purposes for TCSP projects. The purposes are broad and include transportation efficiency, environment, access to jobs, services, and centers of trade, efficient use of existing infrastructure, and land development patterns. A key element of TCSP is exploring the link between transportation and land development patterns. The FHWA is looking for innovative approaches to test and evaluate the effectiveness of integrating land use planning and transportation planning to meet the purposes of TCSP.

Innovation

The TCSP is a small pilot program developing and testing new strategies for use by State and local agencies nationwide in their ongoing transportation programs. Funding in TCSP is not intended to implement community preservation practices nationwide, but to plan, implement, and test new approaches meeting the TCSP program goals. As a pilot program, the TCSP provides the opportunity for agencies to support and encourage non-traditional approaches, and for communities to exchange experiences on new transportation and community preservation strategies.

Evaluation and Results

Evaluation, a key component of the TCSP, requires projects to identify the expected results of the project activities, and apply objective measures to and measure their outcomes and results. This is critical to the success of the pilot program. Only through evaluation, with descriptions of expectations and documentation of results, will other communities be able to learn from the projects and apply the lessons learned. Clearly, stating the project's objectives and activities and anticipated results are important for successful proposals, as are demonstration of how results will be measured, and how evaluation information will be made available to a national audience (e.g., through reports, web-sites, new models, etc.). In addition, successful proposals should include a schedule of the project's major milestones for undertaking completing the project, and conducting project evaluation.

Partnerships

The TCSP encourages public and private participation in proposed projects. In addition, TCSP encourages including non-traditional partners on the project team. The type and scope of the project will determine the best mix of partners and whether these should include members of the general public, as well as environmental, community, business, and other groups. The roles and functions of the partners should also be explained.

FY 2000 TCSP Program

In response to the May 10, 1999, **Federal Register** notice (64 FR 25098–25114) requesting applications for TCSP funding, the FHWA received 292 applications from 48 States and the District of Columbia for $151 million. A complete list of the applicants is available on the TSCP web site: *http://tcsp-fhwa.volpe.dot.gov/*. Under the FY 2000 DOT Appropriations Act, Congress authorized $25 million for 39 special projects and provided an additional $10 million to the TCSP. The FHWA received 292 grant proposals for FY 2000. These proposals are being reviewed and awards are planned to be made in December 1999.

TCSP Resource Working Group

The DOT established the TCSP in cooperation with other Federal agencies, State, regional, and local governments. The FHWA is administering the program and established a working group to assist with program direction. Representatives from the Federal Transit Administration (FTA), the Federal Railroad Administration (FRA), the Research and Special Programs Administration/Volpe Center (RSPA), the Office of the Secretary of Transportation (OST), the Environmental Protection Agency (EPA), and the Department of Housing and Urban Development (HUD) are essential partners in this effort.

Summary of Comments to the Docket

The May 10, 1999, **Federal Register** notice requested comments on the TCSP program implementation in FY 2000 and beyond. The complete docket may be viewed at the locations provided under the captions **ADDRESSES** and Electronic Access in the preamble. The following organizations submitted comments to the docket (FHWA–98–4370): a combined letter on behalf of the Idaho, Montana, North Dakota and Wyoming State Transportation Departments and a letter from the State of California Department of Transportation. The most significant comments are summarized below.

1. Define the role of State and local agencies in the application process.

Comment: Several States recommend that regional and local government applicants pass applications through the appropriate State DOT or MPO for endorsement and approval to ensure that the proposals meet the needs identified in existing plans and to reduce the possibility of duplication.

Response: The FHWA continues to emphasize the importance of project applicants coordinating with the appropriate State DOT or MPO. Such coordination is indicative of well planned project proposals and project partnerships. Applicants are encouraged to coordinate and form partnerships with their State DOT and MPO. Applications to date have shown such coordination.

2. The TCSP program and funding applicants should be consistent with and respect the State and MPO planning processes rather than attempting to redesign the existing processes.

Comment: The TCSP proposals should be consistent with and supported by statewide and metropolitan planning processes. The commenters expressed concern that the TCSP pilot could circumvent the

existing planning processes and proposed that the FHWA should require all applicants to include written confirmation or endorsement from the applicable State or MPO.

Response: The FHWA's commitment to the transportation planning process is established by the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) (Public Law 102–240, 105 Stat. 1914 (1991)) and the TEA–21. As elaborated under Section II below, the TCSP is committed to enhancing the existing planning processes—not to weakening them.

Section II: Request for FY 2001 TCSP Grants

Introduction

The grants funded under the TCSP program will develop, implement, and evaluate transportation strategies supporting transportation and community and system preservation practices which incorporate beneficial short-and long-term environmental, economic, and social equity effects to help build livable communities.

Application Process

Applicants are to submit a 15-page application using the format identified under Attachment I to this notice. The FHWA and a multi-agency technical review panel will review the applications before making recommendations to the Federal Highway Administrator and the USDOT Secretary for final approval.

Funds Availability

Applicants should recognize that the TCSP has limited funding with a high application volume and should develop their budgets accordingly. In FY 1999, several applicants received less funding than requested which caused them to reevaluate and redefine their project's scope. The FHWA sees this as a reality based on the program applicants' funding requests as related to the funds available.

It is appropriate for applicants to request TCSP support for a smaller innovative portion of a larger project which can be funded under other transportation funding. This may also help increase the local matching share committed to the project, a factor in project selection. In addition, leveraging other Federal funds (e.g., EPA, HUD, or other highway and transit funding) as part of a larger project will also demonstrate local commitment to the project.

Grants may be spent over a period of up to two years, but no commitment can be made for subsequent years of grant awards. Thus, phased projects should stand alone and be capable of being implemented and producing results in each phase.

Eligible Recipients

State agencies, MPOs, tribal governments, and units of local governments recognized by a State are eligible recipients of TCSP grant funds. This includes towns, cities, public transit agencies, air resources boards, school boards, and park districts, but not neighborhood groups or developers. While non-governmental organizations are not eligible to receive TCSP funds under section 1221 of TEA–21, these organizations are encouraged to form partnerships with an eligible recipient as the project sponsor.

States or MPOs may be both a project sponsor and endorse other activities proposed and submitted by a local government within its boundary. A State or MPO may consider packaging related activities for submittal as one larger grant request in coordination with the respective project applicants.

Grant Program Purposes

Activities funded under TCSP should address and integrate each of the purposes of the program listed below. Priority will be given to those proposals which most clearly and comprehensively meet and integrate the purposes and are most likely to produce successful results. How well proposed projects achieve each of these purposes will be a principal criterion in selecting proposals for funding. Applicants should develop proposals that specifically address these purposes. Grant proposals should address how proposed activities will meet and integrate all of the following:

1. Improve the Efficiency of the Transportation System

Proposals for TCSP activities should identify, develop, and evaluate new strategies and measures of transportation efficiency that are based on maximizing the use of existing community infrastructure, such as, highways, railroads, transit systems and the built environment. Proposals should address the transportation system as a whole rather than focusing on one mode of transportation. This may include for example, improving the integration of various modes of travel, such as, highway, transit, pedestrian, bicycling, and rail or improving the efficiency of port, rail and highway connections for freight and jobs. Performance measures should include a focus on movement of people and goods and access rather than movement of automobiles, and on services provided rather than vehicle miles traveled.

2. Reduce the Impacts of Transportation on the Environment

Proposals for TCSP activities should explore the long-term direct and indirect social, economic, and environmental impacts of transportation investments on the natural and built environment. Consideration of environmental factors should not be limited to air quality but should also address, if appropriate, ecosystems, habitat fragmentation, water quality, as well as community and cultural issues such as disadvantaged populations and environmental justice. Performance measures should relate the results of TCSP activities to the larger community, regional environment, and the transportation system.

3. Reduce the Need for Costly Future Public Infrastructure

Proposals for TCSP activities should describe how they will reduce the need for costly future public infrastructure investment or create tools and techniques to measure these savings over the life cycle of the activities. Performance measures should include projected life cycle savings obtained through avoiding future investments or maintenance.

4. Ensure Efficient Access to Jobs, Services and Centers of Trade

Proposals for TCSP activities should clearly demonstrate how they improve efficient, affordable access to jobs, services, and centers of trade and address benefits for disadvantaged populations. This could also include the use of new technologies that increase access for people and businesses while reducing the need to travel. Performance measures should include improved access to jobs and services, and improved freight movements.

5. Encourage Private Sector Development Patterns

Proposals for TCSP activities should identify and test effective strategies to encourage private sector investments that result in land development patterns that help meet the goals of this pilot program. Effectively linking land use and transportation is a key feature of TCSP. Performance measures should demonstrate and permit monitoring of changes in development patterns and private sector investment trends or opportunities resulting from TCSP-related activities.

Grant Priorities

In addition to meeting the purposes of the TCSP as discussed above, grant applications are evaluated on the following factors:

1. A Demonstrated Commitment of Non-Federal Resources

Although matching funds are not required, priority will be given to projects which leverage non-Federal funds and take advantage of in-kind contributions, such as, maintenance agreements, land donations, and volunteer time. The contribution of local funds and resources for a project demonstrates local commitment to a project and indicates the likelihood that it will be fully implemented. In addition to non-Federal funds, applicants are encouraged to pursue other Federal resources to support Livability Initiatives such as Transportation Enhancement, Congestion Management and Air Quality funds, as well as HUD, EPA, DOI, and other programs. A description of the President's Livability Initiative can be found on the White House Web site:

http://www.livablecommunities.gov/.

2. An Evaluation Component

The plan to evaluate the project's objectives and outcomes is a key element of the grant proposal. The evaluation plan should include goals, expected outcomes, measures, evaluation methodologies, major evaluation milestones and deliverables for the project. See the discussion on Evaluation in this section.

3. An Equitable Distribution of Grants With Respect to a Diversity of Populations

The FHWA will ensure the equitable geographic and demographic distribution of funds. Applicants should identify and describe who will be served by the project.

4. Demonstrated Commitment to Public and Private Involvement Including the Participation of Non-Traditional Partners in the Project Team

Such partners might include public utility operators, social services agencies, community groups, environmental organizations, non-profit organizations, public health agencies, private land development organizations, and real estate investors. The TCSP also envisions non-traditional partners as active players on the project team who help develop the project's assumptions and scenarios. In the proposal, applicants should describe the roles and commitments of all their partners.

Applicant Category

The TCSP was intended to support localities which have already begun preservation practices and to encourage those areas just starting these practices. The legislation referred to the types of grants being requested as implementation grants and planning grants respectively. To clarify these terms, the following definitions will be used: (a) those just beginning to start community preservation practices—initial stage, or (b) those who have already initiated transportation related community preservation programs and policies—advanced stage. The latter category includes those who have coordinated with State and locally adopted preservation and development plans; integrated transportation and community and system preservation practices; promoted investments in transportation infrastructure and transportation activities that minimize adverse environmental impacts and lower total life cycle costs; or encouraged private sector investments and innovative strategies that address the purposes of the TCSP program.

Eligible Activities

Activities eligible for TCSP funding include activities eligible for Federal highway and transit funding (title 23, U.S.C., or chapter 53 of title 49, U.S.C.) or other activities determined by the Secretary to be appropriate. This allows a broad range of transportation activities to be funded. Grants will be awarded for new and innovative transportation activities meeting the purposes of the TCSP program, but remain unfunded under the current Federal-aid program.

Strategic Priorities

Grants will be awarded for activities which meet the purposes of the program described above and are innovative and can be replicated by others. The goal of the TCSP is to develop a broad range of strategies for urban, suburban, and rural communities which help promote liveable communities through transportation investments and operations. The legislative language that created TCSP is general and provides States, MPOs, tribal governments, and local agencies flexibility to create innovative approaches to address the goals. As the program evolves, the FHWA will use individual project evaluations conducted by grantees, the results of research, and overall program evaluation to determine the strategic priorities for TCSP. Therefore, rather than setting specific strategic priorities, the FHWA is providing information about previously funded projects with suggestions to prospective applicants of FHWA's interest areas. The FHWA continues to seek additional strategies that are innovative and can be replicated by others.

Applicants should highlight innovative and unique aspects of their proposals, and how the results of their proposal will further the purposes of the TCSP. Applicants also should not seek to duplicate previously funded activities unless there is a significant change in the scope, application, or results of the strategy.

The FHWA is also interested in proposals which measure the results and broad impacts on communities of current preservation practices including urban growth boundaries, infill development, and land use changes. Other areas that may be considered include integrating community health and safety goals with transportation to promote livable communities; planning or implementing regional and local strategies to mitigate greenhouse gas emissions; using technology and communications that provide people and businesses with improved access to goods and services to promote livable communities; and enhancing intermodal and freight access to promote economic growth and access to jobs in communities.

The FHWA is particularly interested in supporting projects that are ready to begin and have plans to collect and document results that can be shared with others quickly and successfully. The proposal should highlight when the proposal would be initiated and when results are expected.

Evaluation

Every proposal funded under the grant program should include a description of the applicant's plans for monitoring, evaluating, and analyzing the project and provide the results of the analysis to the FHWA. This information is necessary to provide an opportunity for the DOT, States, MPOs, and local governments to learn more about the practical implications of integrating land development, transportation, and environmental decisionmaking—what works and what doesn't and why for each project. The grant request may include funding for travel for one representative to attend two national workshops to present the plans, status, and results of the project.

The measures used to evaluate project results should be based on the goals and objectives of the project. In addition to individual project evaluations, an overall program evaluation will be conducted by the FHWA under the

research component of the program described in Section III of this notice.

Developing measures to determine the results of the projects is difficult and there is no general consensus on operative measures. A resource guide on program evaluation for TCSP projects and other related information, including references and case studies, are available on the FHWA Web page (*http://tcsp-fhwa.volpe.dot.gov*). Methods to measure and evaluate current and future performance may include, for example:

1. Quantitative assessments, such as, measurement of changes in traffic flow and mode choice (*e.g.*, increased pedestrian and bicycle traffic), environmental impacts and reduced number of trips;

2. Analytic procedures which forecast the current and future impacts of projects, such as, travel demand, land development, or economic forecasting; or

3. Qualitative assessment, such as, interviews, surveys, changes in local ordinances, or other anecdotal evidence.

Relationship of the TCSP to the Transportation Planning Process

The TCSP will complement, strengthen, and enhance the Statewide and MPO planning process created by the ISTEA, and refined by the TEA–21. This process promotes the ongoing, cooperative, and active involvement of the public, transportation providers, public interest groups, and State, metropolitan, and local government agencies in the development of statewide and metropolitan transportation plans and improvement programs (23 CFR part 450).

Applicants should clearly demonstrate their coordination with State and local planning agencies and the project's consistency with appropriate statewide and metropolitan transportation planning processes. To accomplish this, TCSP applicants should coordinate with the appropriate State DOT or MPO to ensure their project is consistent with and doesn't circumvent the planning processes. In addition, the FHWA will post the list of FY 2001 applicants and project proposals on its Web site as soon the information can be compiled.

The DOT fully supports this planning process, which has brought diverse constituencies and government agencies together, and views the TCSP activities as a logical step in the continuing improvement of transportation planning at the State and regional level. The TCSP can help broaden the scope and impact of the planning process to better integrate land development planning, environmental goals and objectives, economic development, social equity considerations, and other private sector activities. The integration of interest groups, investors, and developers through partnering with government applicants is a goal of the program. The TCSP activities also consider incorporation of much longer planning horizons and consider the impacts on future generations.

Activities funded by this program may be used to test or implement new, innovative planning methods and programs that significantly enhance the existing statewide and MPO transportation planning processes. The TCSP funds are intended to leverage new transportation and community preservation initiatives rather than to fund the ongoing planning activities of States and MPOs. In addition, activities should encourage and improve public involvement in the overall planning process, as well as in the individual project.

Construction projects funded by the TCSP will ultimately be included in an approved State or MPO Transportation Improvement Program (TIP). The TCSP funds should not be requested for projects that have already been scheduled for funding and are in the current State or MPO TIP. Highway and transit projects which either use Federal funds or require Federal approvals and are in air quality non-attainment or maintenance areas should be included in an air quality conformity analysis required as part of the transportation planning process. Because TCSP projects may target improved air quality as part of their broader goals, documentation of the beneficial air quality impacts of the project is important.

Non-construction activities funded by the TCSP, such as the development of regional plans and policies, project evaluations, and land development code changes, may not need to appear in a statewide or MPO TIP, but should still have the support or endorsement of the State or MPO. Planning activities funded by TCSP should be reflected in the metropolitan area's Unified Planning Work Program. Non-construction activities may result in changes to existing State and MPO plans and, therefore, need coordination with other jurisdictions within a metropolitan region or State.

Schedule and Administrative Processes

There are several options for the administration of grants under TCSP. The FHWA has a financial management system with the State Departments of Transportation and anticipates that most TCSP grants will be channeled through this established process. However, if another process such as a cooperative agreement or grant through another eligible agency (*e.g.*, a public transit agency) is preferred, the applicant can work with the appropriate FHWA Division Office to develop a different funding mechanism.

Applicants must submit four (4) printed copies of their application and a diskette with the application file to the appropriate FHWA Division office by January 31, 2000. Questions about the grant program should be directed to the FHWA's Division Office in the State in which the applicant is located (Attachment II). The time line for FY 2001 TCSP activities follows:

TCSP FY 2001 TIME LINE

TCSP milestones	FY 2001
Grant applications due to FHWA Division Offices	January 31, 2000.
Research project recommendations due to FHWA	January 31, 2000.
Research projects identified	March 2000.
Grant projects awarded	October 2000.

Section III: Recommendations for FY 2001 TCSP Research

Introduction

The TCSP includes a comprehensive research program to investigate the relationships between transportation, community preservation, and the environment, and to investigate the role of the private sector in shaping such relationships. The research program also includes monitoring, evaluation, and analysis of projects carried out under the grant program.

Program Evaluation and Outreach

Program and project evaluation is an important part of the TCSP. To meet the purposes of the pilot program and develop strategies and methodologies for use by localities, measurable results and a means to disseminate this information are needed. In addition to the evaluation of each project conducted by the grantee, the FHWA will conduct an overall program evaluation combining the results of the grants and the research program to help set the strategic direction and future priorities for the TCSP. An important measure for the success of TCSP is the extent to which the results and best practices from the pilot program are used effectively by government agencies, the private sector, and others.

Under the research component of TCSP, the FHWA will establish outreach, technical assistance, and other means to share and implement the results elsewhere. Current outreach plans include **Federal Register** notices, grant workshops, the FHWA web site information, and participation in other conferences and meetings.

Research Program

The goal of the research program is to build a knowledge base of work in this field to enable State, regional and local government agencies, the private sector, and neighborhood groups, through transportation activities, to shape livable communities which meet current and long-term environmental, social equity, and economic goals. With coordination and input from its partners and stakeholders, the FHWA will identify and initiate needed research to support the purposes of the TCSP. The research program is integral to the TCSP and will support and complement the activities conducted through planning and implementation grants. Likewise, applied research activities that may be a part of a grant activity could benefit the research program.

The FHWA anticipates that most of the TCSP funds will be allocated for grants and that limited funding will be available for the FHWA to undertake research. In addition to FHWA conducted research under the TCSP, the FHWA is soliciting research recommendations for FY 2001 which may be conducted through cooperative agreements with organizations, contract support, or through State, local, and MPO grants. The FHWA is soliciting comments on the research needs to support the TCSP and will initiate research to meet the identified needs.

The FHWA requests research recommendations addressing the following areas:

1. Evaluate Results of Current Community Preservation Practices

Information is needed on the specific outcomes of current statewide, regional, and local community preservation practices, such as, green corridors, smart growth, urban growth boundaries, higher density development, and land use controls to improve transportation efficiency. Research should include both costs and benefits of these initiatives and performance measures.

2. Develop Needed Tools and Methodologies to Support Decision Makers

Transportation-related tools and analytical techniques will be enhanced to help support the State and local decision makers in taking a longer term view and balancing economic, social equity, and environmental goals.

The following information must be included in each abstract for research recommendations or statements of need. The recommendations for initial consideration should be brief, no more than two pages. Follow the outline below and use 12 point type.

1. Title
2. Agency/ or Organization
   Key Contacts
   Address
   Phone/Fax/E-mail
3. Abstract: This should be a brief paragraph describing the research needed, the expected results, and include justification of need and purpose.
4. Methodologies to be used
5. Estimated Costs
6. Potential Resources (expertise and financial)

Selected activities will be requested to develop more detailed proposals explanations.

Attachment I—FY 2001 TCSP Grant Application Format

Project Submission

Four (4) printed copies of the application and a diskette with the application file are due into the FHWA Division office in the applicant's State by COB Monday, January 31, 2000.

The application should be no more than 15 pages in length following the format below. Each application must stand on its own. Do not submit letters of support or additional supporting materials—except maps.

Cover Sheet with Abstract (1 page)

I. Project Information

Project Title And Location:
Agency:
Key Contact:
Address:
Phone/Fax/E-mail:
Amount Requested: $_____
Matching Funds/Services value: $_____.

Abstract

This should be a very brief paragraph describing the project and the expected results. Describe the scale of activity such as rural, urban, statewide, etc. and provide information on the types of populations affected by the project (*i.e.*, size of population, commuter, disadvantaged, minority, etc.).

Sample Abstract

Evaluate the existing buildings, transportation infrastructure, and utilities and the development of a schematic campus master plan with capital costs, an implementation schedule, and funding strategies. Tool Town will make more efficient use of existing transportation network and other infrastructure and reuse land and the built environment, both of which will curb additional regional sprawl. The effort will also create jobs that can be filled by Dayton residents; support the long-term viability of tooling and machining in our region; help tooling and machining industry compete globally; and retain these secure, high-paying jobs in the United States.

II. Project Description

Narrative: Briefly describe the project, the geographic scale of the proposed activity (system, region, corridor, etc.), its expected results in the short- and longer-term (20–40 years), and the applicant's expectations or vision for the ultimate impact of the activity.

III. Purpose and Criteria

Objectives: Further describe the project and its objectives. Relate how it furthers and integrates each of the following purposes of the TCSP program:

1. Improve the efficiency of the transportation system;
2. Reduce the impacts of transportation on the environment;
3. Reduce the need for costly future investments in public infrastructure;
4. Ensure efficient access to jobs, services, and centers of trade; and
5. Examine development patterns and identify strategies to encourage private sector development patterns which achieve the goals of the TCSP.

IV. Applicant Category

Applicants should identify if their agency: (a) Is just beginning community

preservation practices—initial stage, or (b) has implemented community preservation practices—advanced stage. Applicants in the later category should provide brief information on established community preservation practices within their community or jurisdiction.

V. Coordination

Indicate how the appropriate MPO or State Department of Transportation coordination has been undertaken. Identify how the project activities are consistent with the State or MPO planning processes.

VI. Partners

List, and briefly describe if necessary, the agencies, organizations, and companies participating in the activities or on the project team. Describe the role and functions of the non-traditional partners participating on the project team. Describe plans for involvement or education of the private and public sector.

VII. Schedule

Provide a schedule to complete the major steps or milestones in the project. Include dates of major milestones for project activities, the evaluation, and when written reports of the project activities will be submitted.

VIII. Budget and Resources

Include a list all funding, both Federal and non-Federal, and in-kind resources for the project. Priority is given to proposals that demonstrate a commitment of non-Federal resources. Proposals should clearly describe use of in-kind and direct funding contributions and distinguish contributions that are made directly for the proposed projects from those made for other related activities.

The budget should include a list of the major costs by category for the project. This could include, for example, personnel costs, travel, services, project evaluation including any contract services, etc. The budget should also show how the TCSP funds and other matching funds are used for these activities. The budget may include the costs for travel for one representative of the project team to participate and present the status and results of the project at two national conferences.

IX. Project Evaluation Plan

The FHWA has developed guidance on preparing evaluation plans for TCSP. This will assist applicants prepare and summarize their preliminary plans to evaluate the activity, including goals and objectives and evaluation methodologies, including means of monitoring, indicators and measures of performance, and plans for reporting results. Within the limits of space allowed for the proposal, applicants should provide initial ideas on evaluation approaches, which can be expanded and formalized in more complete evaluation plans after awards are made. Copies of this guidance and other related materials on evaluation can be found on the FHWA TCSP website (*http://www.fhwa.dot.gov/program.html*) or from the FHWA's Division office in the applicant's State (see Attachment II):

Submission Format

Because the FHWA will make copies of the grant proposals for the review process, all requests should be in a similar format:

General Information:

Page Size: 8½″ x 11″ (including maps).

12 point font, single sided.

Clip the top left corner—no binding or staples.

Maps should be reproducible in black and white.

Include on each page of your submission the project title and page number.

File format for additional electronic submission:

Electronic Format: WordPerfect version 6/7/8 or Word version 97 or earlier on a 3½ inch floppy disk labeled with the project title and name.

No watermarks, embedded text, or graphics.

ATTACHMENT II.—FHWA DIVISION OFFICES

State	FHWA address, phone number
Alabama	500 Eastern Boulevard, Suite 200, Montgomery, AL 36117–2018, 334–223–7370.
Alaska	P.O. Box 21648, Juneau, AK 99802–1648, 907–586–7180.
Arizona	234 N. Central Avenue, Suite 330, Phoenix, AZ 85004, 602–379–3916.
Arkansas	Federal Office Building, 700 West Capitol Avenue, Room 3130, Little Rock, AR 72201–3298, 501–324–5625.
California	980 9th Street, Suite 400, Sacramento, CA 95814–2724, 916–498–5015.
Colorado	555 Zang Street, Room 250, Lakewood, CO 80228–1097, 303–969–6730, Ext. 371.
Connecticut	628–2 Hebron Avenue, Suite 303, Glastonbury, CT 06033–5007, 860–659–6703, Ext. 3008.
Delaware	300 South New Street, Room 2101, Dover, DE 19904–6726, 302–734–3819.
DC	555 Union Center Plaza, 820 First Street, N.E., Suite 750, Washington, DC 20002, 202–523–0163.
Florida	227 North Bronough Street, Room 2015, Tallahassee, FL 32301, 850–942–9586.
Georgia	61 Forsyth St., SW, 17th Floor, Suite 17T100, Atlanta, GA 30303–3104, 404–562–3630.
Hawaii	300 Ala Moana Boulevard, Suite 3202, Box 50206, Honolulu, HI 96850, 808–541–2531.
Idaho	3050 Lakeharbor Lane, Suite 126, Boise 83703, 208–334–9180, Ext. 119.
Illinois	3250 Executive Park Drive, Springfield, IL 62703–4514, 217–492–4641.
Indiana	Federal Office Building, Room 254, 575 North Pennsylvania Street, Indianapolis, IN 46204–1576, 317–226–7475.
Iowa	105 6th Street, P.O. Box 627, Ames, IA 50010–6337, 515–233–7302.
Kansas	3300 South Topeka Blvd., Suite 1, Topeka, KS 66611–2237, 785–267–7281.
Kentucky	John C. Watts Federal Building and U.S. Courthouse, 330 West Broadway Street, P.O. Box 536, Frankfort, KY 40602, 502–223–6723.
Louisiana	Federal Building, Room 255, 750 Florida St., Room 255, P.O. Box 3929, Baton Rouge, LA 70801, 225–389–0245.
Maine	Edmund S. Muskie Federal Building, 40 Western Avenue, Room 614, Augusta, ME 04330, 207–622–8487, Ext. 20.
Maryland	The Rotunda, Suite 220, 711 West 40th Street, Baltimore 21211–2187, 410–962–4342, Ext. 124.
Massachusetts	Transportation Systems Center, 55 Broadway, 10th Floor, Cambridge 02142, 617–494–3657.
Michigan	Federal Building, Room 207, 315 West Allegan Street, Lansing, MI 48933, 517–377–1844.
Minnesota	Galtier Plaza, Box 75, 175 East Fifth Street, Suite 500, St. Paul, MN 55101–2904, 651–291–6105.
Mississippi	666 North Street, Suite 105, Jackson 39202–3199, 601–965–4223.
Missouri	209 Adams Street, Jefferson City 65101, 573–636–7104.
Montana	2880 Skyway Drive, Helena, MT 59602, 406–449–5303, Ext. 236.
Nebraska	Federal Building, Room 220, 100 Centennial Mall North, Lincoln, NE 68508–3851, 402–437–5521.
Nevada	705 North Plaza Street, Suite 220, Carson City, NV 89701–0602, 775–687–5321.

ATTACHMENT II.—FHWA DIVISION OFFICES—Continued

State	FHWA address, phone number
New Hampshire	279 Pleasant Street, Room 204, Concord, NH 03301–2509, 603–225–1606.
New Jersey	840 Bear Tavern Road, Suite 310, West Trenton, NJ 08628–1019, 609–637–4200.
New Mexico	604 W. San Mateo Road, Santa Fe, NM 87505, 505–820–2022.
New York	Leo W. O'Brien Federal Building, Clinton Avenue & North Pearl Street, 9th Floor, Albany, NY 12207, 518–431–4131.
North Carolina	310 New Bern Avenue, Suite 410, Raleigh, NC 27601, 919–856–4347.
North Dakota	1471 Interstate Loop, Bismark, ND 58501–0567, 701–250–4347.
Ohio	200 North High Street, Room 328, Columbus, OH 43215, 614–280–6896.
Oklahoma	300 N. Meridian, Suite 105 S, Oklahoma City, OK 73107–6560. 405–605–6174.
Oregon	The Equitable Center, Suite 100, 530 Center St., N.E., Salem, OR 97301, 503–399–5749.
Pennsylvania	228 Walnut Street, Room 558, Harrisburg 17101–1720, 717–221–4585.
Puerto Rico	Federico Degetau Federal Building and U.S. Courthouse, Carlos Chardon St., Rm 329, San Juan, PR 00918–1755, 787–766–5600, Ext. 230.
Rhode Island	380 Westminster Mall, Fifth Floor, Providence, RI 02903, 401–528–4560.
South Carolina	Strom Thurmond Federal Building, 1835 Assembly Street, Suite 758, Columbia, SC 29201, 803–765–5282.
South Dakota	The Sibley Building, 116 East Dakota Avenue, Pierre, SD 57501–3110, 605–224–7326, Ext. 3043.
Tennessee	249 Cumberland Bend Drive, Nashville, TN 37228, 615–736–5394.
Texas	Federal Office Building, Room 826, 300 East Eighth Street, Austin, TX 78701, 512–916–5511.
Utah	2520 W. 4700 South, Suite 9A, Salt Lake City, UT 84118, 801–963–0182.
Vermont	Federal Building, 87 State St., P.O. Box 568, Montpelier 05601, 802–828–4433.
Virginia	The Dale Building, Suite 205, 1504 Santa Rosa Road, Richmond 23229, 804–281–5103.
Washington	Suite 501, Evergreen Plaza, 711 South Capitol Way, Olympia, WA 98501, 360–753–9554.
West Virginia	Geary Plaza, Suite 200, 700 Washington Street. E, Charleston, WV 25301–1604, 304–347–5929.
Wisconsin	Highpoint Office Park, 567 D'Onofrio Drive, Madison, WI 53719–2814, 608–829–7506.
Wyoming	1916 Evans Avenue, Cheyenne, WY 82001–3764, 307–772–2004, Ext. 41.

FHWA/FTA METROPOLITAN OFFICES

Office	Address, facsimile number, phone number
New York	6 World Trade Center, Room 320, New York, NY 10048, FAX: 212–466–1939, 212–668–2201. 26 Federal Plaza, Suite 2940, New York, NY 10278–0194, FAX 212–264–8973, 212–668–2170.
Philadelphia	1760 Market St., Suite 510, Philadelphia, Pa 19103, 215–656–7070, FAX: 215–656–7260, 215–656–7111.
Chicago	200 West Adams, Room 2410, Chicago, IL 60606, 312–886–1616, FAX 312–886–0351, 312–886–1604.
Los Angeles	201 N. Figueroa Street, Suite 1460, Los Angeles, CA 90012; 213–202–3950; FAX: 213–202–3961.

Authority: 23 U.S.C. 315; sec. 1221, Pub. L. 105–178, 112 Stat. 107, 221 (1998); 49 CFR 1.48.

Issued on: November 10, 1999.

Kenneth R. Wykle,

Federal Highway Administrator.

[FR Doc. 99–30211 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Office of Motor Carrier Safety

Orders in Motor Carrier Safety Enforcement Cases

AGENCY: Office of Motor Carrier Safety, DOT.

ACTION: Notice of availability of Federal Highway Administration and Office of Motor Carrier Safety decisions and orders, as well as pending cases.

SUMMARY: This document gives notice of the decisions and orders served from September 10, 1993, to the present, as well as pending cases, concerning the Federal Motor Carrier Safety Regulations and the Hazardous Materials Regulations. The orders are those issued by the Associate Administrator for Motor Carriers, the Program Manager, Motor Carrier and Highway Safety, and the Director, Office of Motor Carrier Safety. Also available are decisions rendered by Administrative Law Judges. These decisions, orders, and pending cases may be viewed and copied through the Department of Transportation's Docket Management System (DMS). The Docket Management System is an electronic, image-based database in which all DOT docket information is stored for easy research and retrieval. Information on logging into the Docket Management System in order to retrieve the full text of these decisions is provided under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Mr. Steven B. Farbman, Adjudications Counsel, Federal Highway Administration, (202) 366–1358, 400 Seventh Street, SW., Washington, DC 20590–0001. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: Pursuant to an internal reorganization, the Program Manager, Motor Carrier and Highway Safety, performed the functions previously performed by the Associate Administrator for Motor Carriers. See Order DOT 1100.63B, February 2, 1999. The authority to decide motor carrier safety and hazardous materials cases was redelegated to the Director, Office of Motor Carrier Safety on October 9, 1999. See 64 FR 56270 (October 19, 1999). An additional redelegation was published on October 22, 1999. See 64 FR 58356 (October 29, 1999).

Electronic Access

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the Federal Register's home page at http://www.nara.gov/fedreg and the Government Printing Office's web page at http://www.access.gpo.gov/nara.

The Docket Management System is an electronic, image-based database in which all DOT docket information is stored for easy retrieval. In the near future, users of DMS will be able to search the cases by CFR cite. When this feature is available, we will publish a

notice in the **Federal Register**. To retrieve all motor carrier enforcement dockets, please search under both the Federal Highway Administration and the Office of Motor Carrier Safety.

To log onto the Docket Management System, go to the following Universal Resource Locator (URL): http://dms.dot.gov. This takes the user to the DMS Web Welcome Screen. To retrieve information on a particular case listed in this notice, click on the ''Search'' button and enter the appropriate docket number. It is necessary to enter only the final four numbers. For example, if the docket number were FHWA–99–1111, just enter 1111.

If you do not know the docket number of a case, after clicking on ''Search,'' click on the Docket Search Form. Then click:

(1) Dockets only
(2) FHWA or OMCS under ''Agency''
(3) Non-Rulemaking under ''Category''
(4) Enforcement under ''Subcategory''
(5) Year under ''CY''
(6) Closed, Pending or Any under ''Docket Status''

If you know the Old Docket Number, but not the one that was given to a case by U.S. DOT Dockets, type it in under ''Old Docket Number.'' If you know the case name, but neither the old docket number nor the new docket number, type %case name% in the docket title space. Click on ''Search'' at the top of the page.

A ''hit list'' of dockets will appear. Click on the docket number you want. A ''hit list'' of documents will appear. Click on the document you want. A docket information page will appear. If you want to view that document, scroll down to the bottom of the page, click either ''TIFF'' or ''Adobe PDF'' on the left side of the page. Then click on ''View'' on the right side of the page. To print the image in either TIFF or Adobe PDF document format, please click on File, print.

The following cases may be retrieved using the DMS System:

Docket No.	Name
1993–5373	PGT Trucking, Inc.
1994–5222	Exide Corporation
1994–5223	Michael John Martin
1994–5225	Hahn Transportation, Inc.
1994–5228	Beier Enterprises d/b/a Oroweat Beir Enterprises
1994–5231	National Transportation Service, Inc.
1994–5232	Ten Motor Carrier Safety Cases
1994–5233	F&F Enterpises, Inc.
1994–5234	G&B Leasing, Inc.
1994–5235	Arlington J. Williams, Inc.
1994–5247	Harry Jack Walker, Jr.
1994–5248	Air Freight Specialists, Inc.
1994–5252	E. Earle Downing, Inc.
1994–5253	Rainbow Charter Service
1994–5254	Paul Abbot Trucking
1994–5255	Triple E Transport, Inc.
1994–5256	M.C. Distributors of Alabama, Inc.
1994–5257	Phillips Construction, Inc.
1994–5258	Central States Carriers, Inc.
1994–5260	Robert S. Bickham
1994–5264	House of Raeford Farms, Inc.
1994–5267	Spirit Express of Western NY, Inc.
1994–5270	M&C Trucking, Inc.
1994–5272	W.M. Johnson Truck Lines, Inc.
1994–5274	Siracusa Moving and Storage d/b/a Siracusa Express
1994–5275	Wolverine Sign Works
1994–5276	American Truck and Trailer Repair
1994–5277	Jimmy Settle
1994–5278	G&G Brick Company, Inc.
1994–5279	Prestolock International, Inc. II
1994–5280	Earl Wright d/b/a Wright Contracting
1994–5281	Monson Trucking, Inc.
1994–5283	Kahoe Petroleum Co., Inc.
1994–5284	Jack Sparrowk Livestock
1994–5285	William W. Christensen d/b/a William W. Christensen Trucking.
1994–5297	Atlantic Wine and Spirits
1994–5305	Otto Brehm, Inc.
1994–5307	Cyfers Trucking Co., d/b/a Joseph L. Cyfers
1994–5308	J&M Towing, Inc.
1994–5310	Lenertz, Inc.
1994–5312	Jerry Hammann Transportation, Inc.
1994–5315	Johnny Boyles Trucking Co., Inc.
1994–5324	Saint Trucking Company
1994–5325	Zambelli Fireworks Manufacturing Co.
1994–5326	Cimpi Express Lines, Inc.
1994–5327	Enron Corporation d/b/a Northern Natural Gas Company
1994–5328	Michalak's Gold Coast Transportation Services, Inc.
1994–5329	Hyman Freightways, Inc.
1994–5330	Gorcom Tours, Inc.
1994–5331	Great Coastal Express, Inc.
1994–5333	Olin Wooten Transport Co., Inc.
1994–5343	BD Trucking Co., Inc.
1994–5344	Stephen D. Plummer d/b/a P&P Transport
1994–5346	Crosby Trucking Service, Inc.
1994–5347	Cardinal Industries, Inc.
1994–5348	Perishable Deliveries, Inc.
1994–5349	Roche Manufacturing Co., Inc.
1994–5350	Bicarbolyte Transportation, Inc.
1994–5351	Ladd Transportation, Inc.
1994–5352	Olin's Garden and Market Center d/b/a Olin K Humphreys
1994–5353	V.&S. Pilot Galvanizing, Inc.
1994–5354	Davals Food Distributors, Inc.
1994–5355	Douglas H. West d/b/a West Fuels
1994–5356	Demeritt Brothers Trucking
1994–5358	Executive Express, Inc.
1994–5359	Hays Trucking, Inc.
1994–5360	J.A.T. Enterprises, Inc
1994–5361	Del-Mar-Va Paving Co., Inc.
1994–5362	Industrial Supply House of Greenup, Inc.
1994–5363	Petro-Express, Inc.
1994–5364	Blue Bird Coach Lines, Inc.
1994–5365	Merlino Service Center d/b/a Regis P. Merlina
1994–5366	Cal-Inland, Inc.
1994–5367	S&H Trucking Co., d/b/a Circle M Trucking Co., Inc.
1994–5368	Petro Express, Inc.
1994–5369	T.D.Y. Freight Services, Ltd.
1994–5370	Fellowship of Christians in Action
1994–5371	Uniseal Aluminum Window Products Corporation
1994–5405	Bertoldi Oil Services, Inc.
1994–5406	Greggo and Ferrara, Inc.
1994–5407	Imperial Mold d/b/a Actus Mold, Inc.
1994–5408	Kane Transport, Inc.
1994–5409	Martin Marietta Energy Systems, Inc.
1994–5410	Red Label Express, Inc.
1994–5411	Twin Express, Inc.
1994–5412	W.E.S. Trucking, Inc.
1994–5413	Crosby Trucking, Inc.
1994–6310	Jim Conner Enterprises, Inc.
1994–6312	Lakehead Oil Company, Inc.
1994–6313	Transcontinental Refrigerated Lines
1994–6315	Curtis N. Hite
1994–6318	Priority One Transport Corporation
1994–6320	Landmark Transport, Inc.
1994–6325	Superior Limousine, Inc.
1995–5290	A to Z Transportation, Inc.
1995–5291	American Paving Corporation
1995–5293	Empire Gas Company, Inc.
1995–5294	John W. Mills Trucking
1995–5296	M&S Chemical Inc.
1995–5298	Daniel C. Coleman, President Double C Enterprises, Inc.
1995–5299	Oak Trucking, Inc.
1995–5301	Robert J. Austin
1995–5302	Aulenback, Inc.
1995–5303	Taylor & Taylor Co., Inc.
1995–5306	John H. Montgomery
1995–5309	Daisy Enterprises, Inc.
1995–5311	Willie R. Etheridge Seafood Co.
1995–5313	Ray & Mascari, Inc.
1995–5314	Blackman Oil Company, Inc.
1995–6326	Les Enterprises De Transport Transpel Ltee
1995–6327	Burke Transportation Company
1995–6329	Conica Corporation
1995–6331	E. Goodwin & Sons, Inc.
1995–6332	Jean Volcy
1995–6333	Jos. Natariani & Company, Inc.
1995–6335	Service Line Corporation
1995–6337	Straley Gas Service, Inc.
1995–6341	Schipper's Service, Inc.
1995–6343	Esdras Velez Trucking Co.
1995–6344	Specialties, Inc.

Docket No.	Name
1995–6346	Eslinger Contracting Co., Inc.
1996–5261	Best Brands, Inc.
1996–5262	G & B Supply, Inc.
1996–5323	Alfred Chew and Martha Chew, d/b/a Alfred and Martha Chew Trucking
1996–5335	Justin Transportation, Inc.
1996–5336	Aulenback, Inc.
1996–5339	G&B Leasing Inc., Jetway Carriers, Inc., Eugene Evridge, and Barbara Evridge
1996–6390	National Retail Transportation, Inc.
1997–2361	Peter Pan Bus Lines, Inc.
1997–2363	National Brokers, Inc.
1997–2367	Atnip Design and Supply Center, Inc.
1997–2375	Brooks and Eaton Express, Inc.
1997–2376	R.B. Bator Trucking, Inc.
1997–2377	Langer Transportation Corporation
1997–2378	Richard Shogry
1997–2379	Robin Express, Inc.
1997–2380	Spirit Express of Western New York, Inc.
1997–2381	Sure Transport, Inc.
1997–2383	Robin Express, Inc.
1997–2384	B.J. Express Charter Service
1997–2385	Chincoteague Seafood, Inc.
1997–2386	Kuehne Chemical Company, Inc.
1997–2387	Gajda Trucking Company
1997–2388	DiBari's Red Eagle Express, Inc.
1997–2389	G&L Trucking, Inc.
1997–2391	Fraticelli Trucking Co., Inc.
1997–2392	Mr. Nick's Transportation Service, Inc.
1997–2393	Commodity Carriers, Inc.
1997–2395	Lily Transportation Corporation
1997–2396	Abilene Motor Express, Inc.
1997–2397	Bio-Environmental Services, Inc.
1997–2398	Blue Mack Transport, Inc.
1997–2400	Gunther's Leasing Transport, Inc.
1997–2404	Hitchens Brothers, Inc.
1997–2405	Insulation Inc. d/b/a Environmental Insulation
1997–2406	Petition for Jerry Lee Holly
1997–2408	J.P. Mascaro & Sons, Inc. (a.k.a. Solid Waste Services, Inc.)
1997–2411	Solid Gold Tours, Inc.
1997–2412	Morabito Baking Co., Inc.
1997–2413	All Leasing of Mid-American, Inc.
1997–2414	R & M Trucking Company
1997–2415	R & R Express (KDK Transport, Inc.) and Ronald Reinerch
1997–2416	Regional Enterprises, Inc.
1997–2417	Solomon Tucker, Jr.
1997–2418	Presidential Coach Lines, Inc.
1997–2424	Owens Transfer
1997–2425	R & R Express
1997–2427	East Florida Hauling
1997–2428	Kenneth G. Schuck, Inc.
1997–2429	Leonard S. Thier d/b/a Thetaco
1997–2430	Whitmer Fuels, Inc.
1997–2432	Virginia HiWay Express, Inc.
1997–2433	Williams Equipment Corporation
1997–2435	Bo-Mark Transport, Inc.
1997–2436	Bionomics, Inc.
1997–2437	Dan F. Carey d/b/a DFC Transport
1997–2438	John F. Tilghman & Sons, Inc.
1997–2439	Moore Transportation Services, Inc.
1997–2440	Nationwide Southeast, Inc.
1997–2445	Builders Transport, Inc.
1997–2469	Spring Lake Farm Transportation, Inc.
1997–2470	Star Delivery & Transfer, Inc.
1997–2471	KMCO, Inc.
1997–2472	James Young Green, Inc.
1997–2473	Gulf States Intermodal, Inc.
1997–2474	Ozark Auto Transportation, Inc.
1997–2475	Pencco, Inc.
1997–2476	Ranger Transportation, Inc.
1997–2478	J.H. Walker Trucking, Inc.
1997–2480	D&J Transfer Company
1997–2482	G.E. Robinson Co., Inc.
1997–2483	S & K Trucking, Inc.
1997–2484	Southern Transportation Association Resources, Inc.
1997–2485	Specialties, Inc.
1997–2488	Allometrics, Inc.
1997–2491	Tri-State Transfer, Inc.
1997–2497	Jakobs Brothers Farms
1997–2498	Levy Sign Company, Inc.
1997–2499	Executive Trucking, Inc.
1997–2500	The Gilbert Companies, Inc.
1997–2502	Grand Rapids Transport, Inc.
1997–2504	Dynasty Transportation, Inc.
1997–2507	Celebration Fireworks, Inc. d/b/a Celebration Party Supply
1997–2508	North Shore and Central Illinois Freight Co., Inc.
1997–2509	Quality Distribution Services, Inc.
1997–2510	Southwestern Freight Carriers, Inc.
1997–2511	Lar-No Trucking, Inc.
1997–2519	Arctic Express, Inc.
1997–2520	Rycoff-Sexton, Inc.
1997–2521	Arctic Foods Distribution, Inc.
1997–2524	Nevada Express, Inc.
1997–2531	Roy E. Gasswint
1997–2532	Crupper Transport & Storage Co., Inc.
1997–2533	Van Vliet and Sons, Inc.
1997–2534	Englund Equipment Co., Inc.
1997–2535	Kenneth Pratt d/b/a K & P Trucking
1997–2536	Bernard D. Reimer
1997–2537	Sorenson Grain Co., Inc.
1997–2538	Crupper Transport & Storage Co., Inc.
1997–2539	Western Liquid Express, Inc.
1997–2541	Florilli Corporation
1997–2542	Schuster, Co.
1997–2545	T.M. Brown Trucking, Inc.
1997–2564	Central Freight Lines, Inc.
1997–2565	Genisis Express, Inc.
1997–2566	Border Transportation, Inc., d/b/a Carolina Carbajal
1997–2567	Carroll Ball Transport, Inc.
1997–2570	G & B Supply
1997–2571	Carry Companies of Illinois, Inc.
1997–2593	Deanna Burke
1997–2606	Burlington Northern Railroad Company
1997–2613	Atlas Trailer Rentals, Inc.
1997–2620	William A. Bixler
1997–2654	Kenneth G. Schuck Trucking, Inc.
1997–2692	Empire Transport Co., Inc.
1997–2757	Trailer Shuttle Systems, Inc.
1997–2774	Can-Am Transport, Inc.
1997–2869	Jerry J. Kobs, Inc.
1997–2887	Dixieland Express, Inc.
1997–3071	Lyte Enterprises, Inc.
1997–3082	QDS Transportation Co. Ltd.
1997–3083	Sanford Salvage
1997–3084	Vanguard Transportation Systems, Inc.
1997–3167	Allen Petroleum Co., Inc.
1997–3220	Macera Brothers of Cranston, Inc.
1997–5265	G & B Supply, Inc.
1998–3303	Prarie State Equipment, Inc., d/b/a Petro Steel
1998–3339	Capital Candy Co., Inc.
1998–3578	J.B. Hunt Transport, Inc.
1998–3672	Martin Vachon and Transport Nitram Inc.
1998–3805	Builders Transport, Inc.
1998–3919	Roy's Towing, Inc.
1998–3948	Thomas S. Amoroso
1998–4013	Star Transport, Inc.
1998–4023	FLO CO2, Inc.
1998–4102	P & P Enterprise Company
1998–4391	G.D.C., Inc.
1998–4500	Richard Lee Phipps d/b/a Lee Enterprises
1998–4779	Robert D. Bennett
1998–4818	George Moore Truck & Equipment Corporation
1998–4852	Jonick & Company, Inc.
1998–4941	Wilson Lines, Inc.
1999–5386	Bigbee Transportation, Inc.
1999–5445	Arctic Express Inc.
1999–5481	Dave Kistler & Grandson Trucking, Inc.
1999–5739	Cargo Transport, Inc.
1999–5775	Roel Sarmientios-Ruiz
1999–5840	Dave Kistler & Grandson Trucking, Inc.
1999–6041	Kim Michael Krause
1999–6049	J.C. Bracewell, Jr., Enterprises, Inc.
1999–6053	Roadco Transportation Services, Inc.
1999–6056	Cannonball Express Transportation Co.
1999–6182	Vikramjit Singh d/b/a Singh Trucking
1999–6243	Young Express, Inc.
1999–6277	J.C. Bracewell, Jr., Enterprises, Inc.
1999–6287	Kraftwood, Inc.
1999–6308	North Haven Transportation Company Inc.

Authority: 49 U.S.C. 301 and 322, sec. 338, Pub.L. 106–69, 113 Stat. 986, at 1022).

Issued on: November 10, 1999.

Julie Cirillo,

Acting Director, Office of Motor Carrier Safety.

[FR Doc. 99–30212 Filed 11–18–99; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Specific and Continuing Transportation Bond, Distilled Spirits and/or Wines Withdrawn for Transportation to Manufacturing Bonded Warehouse, Class Six.

DATES: Written comments should be received on or before January 18, 2000 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Joyce Drake, Regulations Division, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8206.

SUPPLEMENTARY INFORMATION:

Title: Specific and Continuing Transportation Bond, Distilled Spirits and/or Wines Withdrawn for Transportation to Manufacturing Bonded Warehouse, Class Six.

OMB Number: 1512–0144.

Form Number: ATF F 2736 (5100.12), ATF F 2737 (5110.67).

Abstract: ATF F 2736 (5100.12) and ATF F 2737 (5110.67) are specific bonds which protect the tax liability on distilled spirits and wine while in transit from one type of bonded facility to another. The bonds identify the shipment, the parties, the date, and the amount of the bond coverage. The record retention requirement for this information collection is 2 years.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 1.

Estimated Time Per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 1.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 12, 1999.

William T. Earle,

Assistant Director (Management) CFO.

[FR Doc. 99–30275 Filed 11–18–99; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Liquors and Articles from Puerto Rico or the Virgin Islands.

DATES: Written comments should be received on or before January 18, 2000 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Jim Ficaretta, Regulations Division, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8203.

SUPPLEMENTARY INFORMATION:

Title: Liquors and Articles from Puerto Rico or the Virgin Islands.

OMB Number: 1512–0494.

Recordkeeping Requirement ID Number: ATF REC 5530/3.

Abstract: This information collection applies to persons bringing nonbeverage products into the United States from Puerto Rico and the Virgin Islands. Recordkeeping requirements are necessary for the verification of claims for drawback of distilled spirits excise taxes paid on such products. The record retention period for this information collection is 3 years.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 20.

Estimated Time Per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 120.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including

through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 12, 1999.

William T. Earle,

Assistant Director (Management) CFO.

[FR Doc. 99–30276 Filed 11–18–99; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Brewer's Bond and Brewer's Bond Continuation Certificate.

DATES: Written comments should be received on or before January 18, 2000 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to William Foster, Regulations Division, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8374.

SUPPLEMENTARY INFORMATION:

Title: Brewer's Bond and Brewer's Bond Continuation Certificate.

OMB Number: 1512–0081.

Form Number: ATF F 5130.22, ATF F 5130.23.

Abstract: The Brewer's Bond is executed by a brewer and surety company to ensure payment of the excise tax on beer removed from the brewery. The Brewer's Bond Continuation Certificate is executed by a brewer and surety company to continue in effect the coverage of a Brewer's Bond by the surety company.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 280.

Estimated Time Per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 280.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 12, 1999.

William T. Earle,

Assistant Director (Management) CFO.

[FR Doc. 99–30277 Filed 11–18–99; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Application For an Industrial Alcohol User Permit and Industrial Alcohol Bond.

DATES: Written comments should be received on or before January 18, 2000 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Mary Wood, Regulations Division, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8210.

SUPPLEMENTARY INFORMATION:

Title: Application For an Industrial Alcohol Users Permit and Industrial Alcohol Bond.

OMB Number: 1512–0137.

Form Number: ATF F 5150.22, ATF F 5150.25.

Abstract: ATF F 5150.22 is used to determine the eligibility of the applicant to engage in certain operations and the extent of the operations for the production and distribution of specially denatured spirits (alcohol/rum). This form identifies the location of the premises and establishes whether the premises will be in conformity with Federal laws and regulations. ATF F 5150.25 provides notification that sufficient bond coverage has been obtained prior to the issuance of a permit.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 738.

Estimated Time Per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 1,476.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate

of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 12, 1999.

William T. Earle,

Assistant Director (Management) CFO.

[FR Doc. 99–30278 Filed 11–18–99; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Applications, Notices, and Permits Relative to Importation and Exportation of Distilled Spirits, Wine, and Beer, Including Puerto Rico and Virgin Islands.

DATES: Written comments should be received on or before January 18, 2000 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Marjorie Ruhf, Regulations Division, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8202.

SUPPLEMENTARY INFORMATION:

Title: Applications, Notices, and Permits Relative to Importation and Exportation of Distilled Spirits, Wine, and Beer, Including Puerto Rico and Virgin Islands.

OMB Number: 1512–0530.

Abstract: Beverage alcohol, industrial alcohol, beer and wine are taxed when imported. The taxes on these commodities coming from the Virgin Islands and Puerto Rico are largely returned to these insular possessions. Exports are mainly tax free. These sections ensure that proper taxes are collected and returned according to law. The record retention requirement for this information collection is 3 years.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 20.

Estimated Time Per Respondent: 9 hours.

Estimated Total Annual Burden Hours: 180.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 12, 1999.

William T. Earle,

Assistant Director (Management) CFO.

[FR Doc. 99–30279 Filed 11–18–99; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Power of Attorney.

DATES: Written comments should be received on or before January 18, 2000 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Joan Kravchak, Revenue Operations Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–6993.

SUPPLEMENTARY INFORMATION:

Title: Power of Attorney.

OMB Number: 1512–0079.

Form Number: ATF F 5000.8.

Abstract: ATF F 5000.8 delegates authority to a specific individual to sign documents on behalf of an applicant or principal (alcohol and tobacco permittees). Many of the documents that are submitted to ATF entail binding legal commitments by the applicant/permittee and any omission or falsification may subject the applicant/permittee to penalties provided in the law.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 5,000.

Estimated Time Per Respondent: 18 minutes.

Estimated Total Annual Burden Hours: 3,000.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the

agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 12, 1999.

William T. Earle,

Assistant Director (Management) CFO.

[FR Doc. 99–30280 Filed 11–18–99; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Alcohol, Tobacco and Firearms Tax Returns, Claims and Related Documents.

DATES: Written comments should be received on or before January 18, 2000 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Joan Kravchak, Revenue Operations Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–6993.

SUPPLEMENTARY INFORMATION:

Title: Alcohol, Tobacco and Firearms Tax Returns, Claims and Related Documents.

OMB Number: 1512–0492.

Recordkeeping Requirement ID Number: ATF REC 5000/24.

Abstract: ATF is responsible for the collection of excise taxes on firearms, ammunition, distilled spirits, wine, beer, cigars, cigarettes, chewing tobacco, snuff, cigarette papers, tubes and pipe tobacco. Alcohol, tobacco, firearms and ammunition excise taxes, plus alcohol, tobacco, and firearms special occupational taxes are required to be collected on the basis of a return. 26 U.S.C. 5555 authorizes the Secretary of Treasury to prescribe the regulations requiring every person laiable for tax to prepare any records, statements or returns as necessary to protect the revenue. The record retention requirement for this information collection is 3 years.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Business or other for-profit, individuals or households, not-for-profit institutions.

Estimated Number of Respondents: 503,921.

Estimated Time Per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 503,921.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 12, 1999.

William T. Earle,

Assistant Director (Management) CFO.

[FR Doc. 99–30281 Filed 11–18–99; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 2290

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 2290, Heavy Highway Vehicle Use Tax Return.

DATES: Written comments should be received on or before January 18, 2000, to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Heavy Highway Vehicle Use Tax Return.

OMB Number: 1545–0143.

Form Number: 2290.

Abstract: Form 2290 is used to compute and report the tax imposed by Internal Revenue Code section 4481 on the highway use of certain motor vehicles. The information is used to determine whether the taxpayer has paid the correct amount of tax.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 500,625.

Estimated Time Per Respondent: 38 hours, 38 minutes.

Estimated Total Annual Burden Hours: 19,343,363.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to

respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 10, 1999.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 99–30179 Filed 11–18–99; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

[AC–11: OTS Nos. 0210 and H–3537]

Mutual Federal Savings Bank, Muncie, IN; Approval of Conversion Application

Notice is hereby given that on November 10, 1999, the Director, Office of Examination & Supervision, Office of Thrift Supervision, or his designee, acting pursuant to delegated authority, approved the application of Mutual Federal Savings Bank, Muncie, Indiana, Indiana, to convert to the stock form of organization. Copies of the application are available for inspection at the Dissemination Branch, Office of Thrift Supervision, 1700 G Street, NW, Washington, DC 20552, and the Central Regional Office, Office of Thrift Supervision, 200 West Madison Street, Suite 1300, Chicago, Illinois 60606.

Dated: November 16, 1999.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 99–30288 Filed 11–18–99; 8:45 am]

BILLING CODE 6720–01–P

UTAH RECLAMATION MITIGATION AND CONSERVATION COMMISSION

Notice of Finding of No Significant Impact for the Strawberry Aqueduct and Collection System Angler-Access Acquisition and Corridor Management

AGENCY: The Utah Reclamation Mitigation and Conservation Commission.

ACTION: Notice of Finding of No Significant Impact (FONSI).

SUMMARY: On November 17, 1999, Michael C. Weland, Executive Director of the Utah Reclamation Mitigation and Conservation Commission (Mitigation Commission), signed the Finding of No Significant Impact (FONSI), which documents the decision to fund and complete the Angler-Access Acquisition and Corridor Management project. The project is located in Duchesne County and Wasatch County, Utah. The Mitigation Commission and Bureau of Reclamation, joint-lead agencies for the project, documented the environmental effects of funding and completing this project in a 1999 environmental assessment (EA). The Draft EA was issued on July 31, 1998, analyzing the environmental impacts of completing the remaining angler-access and terrestrial wildlife mitigation acquisitions and establishing long-term management guidelines for mitigation lands. The Final EA was refined based upon public comment and released in November 1999. The Mitigation Commission has reviewed the Final EA, determined it adequate for the decisions to be made, and issued a FONSI, in accordance with the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*).

Acquisition and management of angler access corridors are required by the 1988 Supplement to the Definite Plan Report (DPR) for the Bonneville Unit, Central Utah Project (CUP), and/or authorized by the Central Utah Project Completion Act of 1992 (Titles II through VI of Pub. L. 102–575). The Strawberry Aqueduct and Collection System (SACS), a component of the Bonneville Unit, Central Utah Project, consists of a series of pipelines, tunnels, aqueducts and reservoirs that capture water from the Colorado River Basin and divert it to the Bonneville Basin for use along the populated Wasatch Front in Utah. Construction and operation of the Strawberry Aqueduct and Collection System altered stream flows on approximately 240 miles of ten streams. Following years of discussion, a mitigation program was developed for SACS in 1988. To mitigate the impacts, several key agreements were made (including the Aquatic, Wildlife and Wetland Mitigation Plans), and legislation was enacted identifying a mitigation program. A portion of the entire mitigation program for SACS is fulfilled by the Angler-Access Acquisition and Corridor Management project. Specifically, public angler access would be acquired to replace lost angling opportunities. Fifty-one miles of angler access on specific stream reaches was identified for acquisition. Angler access would be acquired where instream flows were provided and in some instances, where stream habitat improvements were made (both mitigation measures of the SACS project). Wetland and riparian woodland mitigation was required on SACS-area streams for impacts caused by construction and operation of the Municipal and Industrial (M&I) System of the Bonneville Unit. Terrestrial habitats impacted by Bonneville Unit features are required to be mitigated for by acquiring and managing uplands (some of which are adjacent to the angler access corridors) for wildlife purposes.

Approximately 42.9 of the 51 miles identified on specific stream reaches for angler-access acquisition have been acquired by the Bureau of Reclamation and the Mitigation Commission. Approximately 8.1 miles remain to be acquired. Approximately 26,728 acres of riparian and upland habitat have been acquired as terrestrial wildlife mitigation in or adjacent to the angler-access corridors. Approximately 490 acres remain to be acquired and managed to fulfill the terrestrial wildlife mitigation requirement. Approximately 126.5 acres of wetlands have been acquired in the angler-access corridors, completing the wetland acquisition mitigation responsibilities associated with SACS.

After reviewing the EA, Biological Assessment, and public and agency comments, the Mitigation Commission has decided to implement the Modified Proposed Action as described in the Final EA. Under the Modified Proposed Action, the Bureau of Reclamation and Mitigation Commission will acquire an additional 8.1 river miles of angler access on specified river reaches and a minimum of 490 acres of specified adjacent uplands and will establish a management framework for the angler-

access corridors. The Mitigation Commission selected the Modified Proposed Action for implementation because it minimizes the impacts on private property owners while achieving the underlying need for the project. The Bureau of Reclamation will use its eminent domain authority to complete the acquisitions only as a last resort, following other reasonable attempts to acquire lands and interests on a willing-seller basis. The environmental effects of the Modified Proposed Action were similar to the impacts of other alternatives analyzed. Implementation of the Modified Proposed Action will achieve the following objectives:

1. Complete outstanding mitigation responsibilities of the Aquatic Mitigation Plan by acquiring an additional 8.1 miles of angler-access.

2. Complete the Wildlife Mitigation Plan by acquiring 490 acres of upland habitat remaining as terrestrial wildlife mitigation.

3. Satisfy the Aquatic Mitigation Plan, Wildlife Mitigation Plan and Wetland Mitigation Plan by protecting and managing mitigation lands for their riparian, wetland, and aquatic resource values. Establish management guidelines and objectives for each of the angler-access corridors.

4. Provide continuous public access throughout angler-access corridors and identify the appropriate level of infrastructure development (parking areas and restrooms) for public use.

FOR FURTHER INFORMATION CONTACT: Additional information about this **Federal Register** notice can be obtained at the address and telephone number below:

Mr. Richard Mingo, Natural Resource Specialist, Utah Reclamation Mitigation and Conservation Commission, 102 West 500 South, Suite 315, Salt Lake City, UT 84101, Telephone: (801) 524–3146.

Dated: November 15, 1999.

Michael C. Weland,

Executive Director.

[FR Doc. 99–30261 Filed 11–18–99; 8:45 am]

BILLING CODE 4310–05–P

Corrections

Federal Register

Vol. 64, No. 223

Friday, November 19, 1999

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF DEFENSE

48 CFR Parts 201 and 213

[DFARS Case 99–D002]

Defense Federal Acquisition Regulation Supplement; Overseas Use of the Purchase Card

Correction

In rule document 99–27278 beginning on page 56704, in the issue of Thursday, October 21, 1999, make the following correction:

213.301 [Corrected]

On page 56705, in the second column, in 213.301(2)(i), the paragraph designation reading ''(1)'' should read ''(i)''.

[FR Doc. C9–27278 Filed 11–18–99; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-41719; File No. SR-NSCC-99-10]

Self-Regulatory Organizations; The National Securities Clearing Corporation; Notice of Filing of Proposed Rule Change Relating to Arrangements to Integrate the National Securities Clearing Corporation and The Depository Trust Company

August 9, 1999.

Correction

In notice document 99–21193, beginning on page 44569, in the issue of Monday, August 16, 1999, make the following correction:

On page 44571, in the first column, in the first full paragraph, in the first line, ''commission'' should read ''Commission''.

[FR Doc. C9–21193 Filed 11-18-99; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES EXCHANGE COMMISSION

[Release No. 34-41721; File No. SR-Amex-98-31]

Self-Regulatory Organizations; American Stock Exchange LLC; Order Approving Proposed Rule Change and Amendment Nos. 1 and 2 Thereto and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 3 to the Proposed Rule Change Relating to Options on the Cure for Cancer Common Stock Index

August 10, 1999

Correction

In notice document 99–21361, appearing on page 44976, in the issue of Wednesday, August 18, 1999, make the following correction:

On page 44976, in the second column, the date line is corrected to read as set forth above.

[FR Doc. C9–21361 Filed 11-18-99; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC-23997; File No. 812-11730]

Transamerica Occidental Life Insurance Company, et al.

September 8, 1999.

Correction

In notice document 99–23992, appearing on page 50121, in the issue of Wednesday, September 15, 1999, make the following correction:

On page 50121, in the third column, the date line is corrected to read as set forth above.

[FR Doc. C9–23992 Filed 11-18-99; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-41968; File No. SR-CHX-99-08]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment No. 1 to the Proposed Rule Change by the Chicago Stock Exchange, Inc., Relating to Access to an After-Hours Trading Session

September 30, 1999.

Correction

In notice document 99–26155, appearing on page 54701, in the issue of Thursday, October 7, 1999, make the following correction:

On page 54701, in the first column, the date line is corrected to read as set forth above.

[FR Doc. C9–26155 Filed 11-18-99; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-42026; File No. SR-CBOE 99-43]

Self-Regulatory Organizations; Order Approving a Proposed Rule Change and Notice of Filing and Accelerated Approval of Amendment Nos. 1, 2, and 3 to the Proposed Rule Change by the Chicago Board Options Exchange, Inc. to Amend its Constitution Pertaining to Corporate Governance

October 18, 1999.

Correction

In notice document 99–27715, appearing on page 54799, in the issue of Monday, October 25, 1999, make the following correction:

On page 57499, in the third column, the docket number is corrected to read as set forth above.

[FR Doc. C9–27715 Filed 11-18-99; 8:45 am]

BILLING CODE 1505–01–D

Friday
November 19, 1999

Part II

Environmental Protection Agency

40 CFR Part 261

Hazardous Waste Identification Rule (HWIR): Identification and Listing of Hazardous Wastes; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[FRN–6469–9]

RIN 2050–AE07

Hazardous Waste Identification Rule (HWIR): Identification and Listing of Hazardous Wastes

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule and request for comments.

SUMMARY: Today's action proposes to retain and amend the mixture rule and the derived-from rule in the Resource Conservation and Recovery Act (RCRA). The mixture and derived-from rules ensure that hazardous wastes that are mixed with other wastes or that result from the treatment, storage or disposal of hazardous wastes do not escape regulation and thereby cause harm to human health and the environment.

EPA is proposing two revisions to the mixture and derived-from rules. These revisions would narrow the scope of the mixture and derived-from rules, tailoring the rules to more specifically match the risks posed by particular wastes. The first is an exemption for mixtures and/or derivatives of wastes listed solely for the ignitability, corrosivity, and/or reactivity characteristics. The second is a conditional exemption from the mixture and derived-from rules for ''mixed wastes'' (that is, wastes that are both hazardous and radioactive).

Today's document also discusses an implementation framework for an exemption from hazardous waste management for wastes that meet chemical-specific exemption levels, also known as the Hazardous Waste Identification Rule (HWIR) exemption. The HWIR exemption would identify a broad set of listed hazardous waste that could be safely managed in nonhazardous waste management units. The current version of the model that could be used to derive the exemption levels is designed to evaluate simultaneous exposures across multiple media and pathways in order to estimate the resulting health and environmental effects. Before using a revised risk assessment to support a final regulatory action, we would propose the HWIR exemption, providing public notice and the opportunity to comment on the revised risk assessment and resulting exemption levels.

In addition, today's document discusses the possibility of revising the Land Disposal Restrictions (LDRs) by replacing technology-based treatment standards in the RCRA regulations with risk-based treatment standards.

DATES: To make sure we consider your comments on revisions to the mixture and derived-from rules (Sections I–IV, Sections XXI–XXVI (as applicable) of the preamble and proposed regulatory language amending 40 CFR part 261), they must be postmarked on or before February 17, 2000.

To make sure we consider your comments on the discussed concentration-based HWIR exemption and the possible revisions to the LDR Treatment Standards (Sections V–XX and Sections XXI–XXVI (as applicable) of the preamble), they must be postmarked on or before May 17, 2000.

ADDRESSES: Please send an original and two copies of your comments referencing Docket number F–99–WH2P–FFFFF to (1) if using regular U.S. Postal Service mail: RCRA Docket Information Center, Office of Solid Waste (5305W), U.S. Environmental Protection Agency Headquarters (EPA, HQ), 401 M Street, S.W., Washington, D.C.. 20460, or (2) if using special delivery, such as overnight express service: RCRA Docket Information Center (RIC), Crystal Gateway One, 1235 Jefferson Davis Highway, First Floor, Arlington, Virginia 22202. It would also be helpful, although not mandatory, to include an electronic copy by diskette or Internet email. In this case, send your comments to the RCRA Information Center on labeled personal computer diskettes in ASCII (TEXT) format or a word processing format we can convert to ASCII (TEXT). Please include on the disk label the name, version, and edition of your word processing software as well as your name and docket number F–99–WH2P–FFFF. Protect your diskette by putting it in a protective mailing envelope. To send a copy by Internet email, address it to: *rcra-docket@epamail.epa.gov.* Make sure this electronic copy is in an ASCII format that doesn't use special characters or encryption. Cite the docket Number F–99–WH2P–FFFFF in your electronic file.

The RCRA Information Center is located at Crystal Gateway One, 1235 Jefferson Davis Highway, First Floor, Arlington Virginia. If you would like to look at and copy supporting information for RCRA rules, please make an appointment with the RCRA Information Center by calling (703) 603–9230. Docket hours are from 9 A.M. to 4 P.M. Monday through Friday, except for Federal holidays. You may copy up to 100 pages from any regulatory document at no cost. Additional copies cost $0.15 per page.

FOR FURTHER INFORMATION CONTACT: For general information about this proposed rule, contact the RCRA Hotline, Office of Solid Waste, U.S. Environmental Protection Agency, Washington, DC 20460, (800) 424–9346 (toll free); TDD (800) 553–7672 (hearing impaired); in the Washington, D.C. metropolitan area the number is (703) 412–9810; TDD (703) 486–3323 (hearing impaired). For technical information on this proposed rule, contact Adam Klinger at (703) 308–3267 or Tracy Atagi at (703) 308–8672; for specific information on the risk modeling system, contact David Cozzie at (703) 308–0479. To get copies of the reports or other materials referred to in this proposal, contact the RCRA Docket at the phone number or address listed above.

SUPPLEMENTARY INFORMATION: The proposal and other material associated with this action can be electronically accessed on the Internet at http://www.epa.gov/epaoswer/hazwaste/id

The official record for this rulemaking will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into paper form and place them in the official record, which will also include all comments submitted directly in writing. The official record is the record maintained at the address in **ADDRESSES** at the beginning of this document.

We will respond to submitted comments, whether written or electronic, in a notice in the **Federal Register** or in a response to comments document placed in the official record for this rulemaking. We will not immediately reply to electronically submitted comments other than to seek clarification of comments that may be garbled in transmission or during conversion to paper form, as discussed above.

Affected Entities

Entities potentially affected by this proposed action are generators of industrial hazardous waste, and entities that treat, store, transport and/or dispose of these wastes. Different sets of entities (*i.e.*, industrial and service sectors) are affected by different provisions of this regulatory proposal, as displayed below: This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action.

SIC code	NAICS code	List of potentially affected U.S. industrial entities
A. Proposed Revision to 40 CFR 261.3 RCRA Mixture-and-Derived-from Rules:		
2800	32xxxx	Chemicals & allied products manufacturing.
2819	Five possible codes	Industrial inorganic chemicals manufacturing.
2821	325211	Plastics materials & resins manufacturing.
2833	325411	Medicinal chemicals & botanicals manufacturing.
2834	325412	Pharmaceutical preparations manufacturing.
2851	32551	Paints & allied products manufacturing.
2869	Five possible codes	Industrial organic chemicals manufacturing.
2879	32532	Pesticides & agricultural chemicals manufacturing.
3089	Four possible codes	Plastics products manufacturing.
3241	32731	Hydraulic cement products manufacturing.
3479	Four possible codes	Fabricated metal coating & allied services.
3711	Five possible codes	Motor vehicle & passenger car bodies manufacturing.
4212	562111 & 562112	Local trucking services (industrial waste shipment).
4953	Five possible codes	Refuse (industrial waste) treatment/disposal services.
7389	36 possible codes	Business services.
7532	811121	Auto repair & auto paint shops.
9511	92411	Waste management.
9711	811121	National security (military bases).

Explanatory Notes:
(1) SIC = 1987 Standard Industrial Classification system (U.S. Department of Commerce's traditional code system last updated in 1987).
(2) NAICS = 1997 North American Industrial Classification System (U.S. Department of Commerce's new code system as of 1997).
(3) Refer to the Internet website *http://www.census.gov/epcd/www/naicsdev.htm* for additional information and a cross-walk table for the SIC and NAICS codes systems.

This table lists those entities that EPA believes could be affected by this proposed action, based on industrial sectors identified in the economic analysis in support of this proposal. A total of about 120 entities are expected to benefit from the proposed revisions to 40 CFR 261.3 in the 17 industrial sectors listed above, but primarily in the chemicals and allied products sector (*i.e.*, SIC code 28, or NAICS code 325). Other entities not listed in the table also could be affected. To determine whether your facility is regulated by this action, you should examine 40 CFR parts 260, 261 and 268 carefully in concert with the amended rules found at the end of this **Federal Register** document. If you have questions regarding the applicability of this action to a particular entity, consult the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

ACRONYMS

Acronym	Definition
3MRA	Multimedia, Multipathway and Multireceptor Risk Assessment.
AOI	Area of Interest.
APA	Administrative Procedures Act.
AT	Aerated Tank.
BDAT	Best Demonstrated Available Technology.
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act.
CFR	Code of Federal Regulations.
CMA	Chemical Manufacturers Association.
CWA	Clean Water Act.
DOT	Department of Transportation.
EPA	Environmental Protection Agency.
EPACMTP	EPA's Composite Model for Leachate Migration with Transformation Products.
EXAMS	Exposure Analysis Modeling System.
EXAMSIO	Exposure Analysis Modeling System—Input Output Interface.
FRAMES	Framework for Risk Analysis in Multimedia Environmental Systems.
GIRAS	Geographic Information Retrieval and Analysis System.
HEAST	Health Effects Assessment Summary Table.
HQ	Hazard Quotient.
HSWA	Hazardous and Solid Waste Amendments of 1984.
HWIR	Hazardous Waste Identification Rule.
HWIR99	Hazardous Waste Identification Rule—1999 Framework.
ICR	Information Collection Request.
IEUBK	Integrated, Exposure, Uptake and BioKinetic Model.
IRIS	Integrated Risk Information System.
ISCST3	Industrial Source Complex Short Term model.
LAU	Land Application Unit.
LCR	Lead and Copper Rule.
LDR	Land Disposal Restriction.
LF	Landfill.
LLMW	Low Level Mixed Wastes.
LLRWDF	FLow Level Radioactive Waste Disposal Facility.
LOEL	Lowest Observed Effects Level.

ACRONYMS—Continued

Acronym	Definition
MACT	Maximum Achievable Control Technology.
MCL	Maximum Containment Level.
MINTEQA2	Geochemical speciation model; originally a combination of Mineral Equilibrium Model (MINEQL) and the thermodynamic database WATEQ3.
NAPL	Non-Aqueous Phase Liquid.
NOEL	No Observed Effects Level.
NRC	Nuclear Regulatory Commission (NRC).
NTTAA	National Technology Transfer and Advancement Act.
OMB	Office of Management and Budget.
ORD	Office of Research and Development.
OIRM	Office of Information and Resources Management.
OSW	Office of Solid Waste.
OSWER	Office of Solid Waste and Emergency Response.
PBMS	Performance Based Measurement System.
QA/QCl	Quality Assurance/Quality Control.
RCRA	Resource Conservation Recovery Act.
RfD	Reference Dose.
RfC	Reference Concentration.
RIC	RCRA Docket Information Center.
RMS	Root Mean Square.
SAB	Science Advisory Board.
SAMSON	Solar and Meteorological Surface Observation Network.
SBREFA	Small Business Regulatory Enforcement Fairness Act.
SCIM	Sampled Chronological Input Model.
SI	Surface Impoundment.
SPARC	System Performs Automated Reasoning in Chemistry.
SSLs	Soil Screening Levels.
SVOC	Semi-Volatile Organic Compound.
SZM	Saturated Zone Module.
TC	Toxicity Characteristic.
TCLP	Toxicity Characteristic Leaching Procedure.
TDD	Telecommunications Device for the Deaf.
TOC	Total Organic Carbon.
TRI	Toxic Release Inventory.
TSCA	Toxic Substance Control Act.
TSDF	Treatment, Storage, and Disposal Facility.
TSS	Total Suspended Solid.
UMRA	Unfunded Mandates Reform Act.
USLE	Universal Soil Loss Equation.
UTS	Universal Treatment Standards.
VO	Volatile Organics.
VOC	Volatile Organic Compounds.
VZM	Vadose Zone Module.
WMU	Waste Management Unit.
WP	Waste Pile

Outline

Background

I. Under what legal authority is EPA proposing these regulatory changes?
II. What is EPA proposing today and on what other actions is EPA seeking comment?

Retaining the Mixture and Derived-From Rules

III. Why is EPA proposing to retain the mixture and derived-from rules?

Proposed Revisions to 40 CFR 261.3

IV. How and why is EPA proposing to revise the hazardous waste identification regulations for mixtures and derived-from wastes?

HWIR Exemption Options

V. Why is EPA developing a chemical-based HWIR exemption for listed hazardous waste (including both mixtures and derived-from waste)?
VI. What options is EPA developing for the HWIR exemption?
VII. What wastes would be eligible for an HWIR exemption?
VIII. What level of governmental review would be needed for an HWIR exemption claim?
IX. For the generic HWIR exemption, what steps would I follow before my waste could be exempted?
X. Once the waste becomes exempt, what RCRA requirements might still apply?
XI. For the generic HWIR exemption, what conditions and requirements would I be required to fulfill to maintain the exemption?
XII. What would be the conditions and requirements for the landfill-only HWIR exemption?
XIII. What would happen if I do not comply with the conditions and the requirements of the HWIR exemption?
XIV. What might the regulatory language for the HWIR exemption look like?

HWIR Risk Assessment

XV. What is the goal of the HWIR risk assessment?
XVI. How did EPA develop the current version of the HWIR risk assessment?
XVII. What are the results of the current version of the risk assessment?
XVIII. How was the HWIR exemption list of chemicals developed?
XIX. How would EPA use the results of the risk assessment to set HWIR exemption levels?

Possible Revision to LDR Treatment Standards

XX. How might EPA use the results of the HWIR model to revise the hazardous waste LDR treatment standards?

Economic Impacts

XXI. What are the economic impacts of today's proposed regulatory changes?

Relationship to Other Programs

XXII. How would the HWIR exemption relate to other programs?
A. Would HWIR change how you determine if a waste is hazardous?
B. Could a characteristic hazardous waste be exempt under HWIR?
C. How would the HWIR exemption differ from the delisting process per 40 CFR 260.22?
D. How would HWIR affect TSDF closure requirements for my facility?
E. How would HWIR affect the Land Disposal Restriction (LDR) Program?
F. How would HWIR relate to the RCRA air emission standards?
G. Would HWIR affect ''Use Constituting Disposal'' regulations?
H. Could hazardous waste debris become under HWIR?
I. Would contaminated media be eligible for an HWIR exemption?
J. Does the final HWIR-Media Rule impact HWIR?
K. How would HWIR impact actions under the Superfund program (CERCLA)?
L. How does HWIR relate to the draft Industrial D Voluntary Guidance?
M. How does HWIR relate to the Comparable Fuels Exemption?
N. How would HWIR affect mixed waste?
O. How does HWIR relate to the Sewage Sludge Regulatory Program?

State Authorization

XXIII. How would today's proposed regulatory changes be administered and enforced in the States?

Administrative Requirements

XXIV. How has EPA fulfilled the administrative requirements for this proposed rulemaking?
A. Executive Order 12866: Determination of Significance
B. Regulatory Flexibility Act
C. Paperwork Reduction Act (Information Collection Request)
D. Unfunded Mandates Reform Act
E. Executive Orders on Federalism
F. Executive Order 13084: Consultation and Coordination with Indian Tribal Governments
G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
H. National Technology Transfer and Advancement Act of 1995

References

XXV. What are some key documents containing information supporting this notice?

Request for Comment

XXVI. On what issues is EPA specifically seeking public comment?

Background

I. Under What Legal Authority Is EPA Proposing These Regulatory Changes?

These regulations are proposed under the authority of Sections 2002(a), 3001, 3002, 3004, and 3006 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. § 6912(a), 6921, 6922, 6924, 6926.

II. What Is EPA Proposing Today and on What Other Actions Is EPA Seeking Comment?

A. What Is Included In Today's Notice?

Today EPA:

1. Proposes to retain the mixture and derived-from rules, currently set forth in 40 CFR 261.3(a)(2)(iii), 261.3(a)(2)(iv) and 261.3(c)(2)(i). As explained in Section III, these rules, which are currently in effect on an emergency basis, regulate wastes that are mixed with, or are derived from the treatment, storage, or disposal of, listed hazardous wastes.

2. Proposes to narrow the scope of the mixture and derived-from rules by exempting mixtures and derivatives of wastes listed solely for the ignitability, corrosivity, and/or reactivity characteristics which no longer exhibit any characteristic of hazardous waste and comply with land disposal restrictions applicable to characteristic wastes.

3. Discusses an implementation framework for two exemptions from Subtitle C management requirements for wastes meeting a set of conditions and procedures. The two options are:

(a) A ''generic'' exemption that has no specific requirements as to how the waste is managed once conditions of the exemption are met; and

(b) a ''landfill-only'' exemption that limits the subsequent management of the exempted waste to disposal in a landfill and prohibits placement on the land before disposal;

4. Discusses the current version of the risk assessment that EPA intends to use to create exemption levels to be used in the implementation framework; and

5. Discusses whether to revise the Land Disposal Restrictions by replacing the technology-based treatment standards in 40 CFR 268.40 and 268.48 with risk-based treatment standards.

B. What Related Regulatory Action Is EPA Also Proposing Elsewhere in Today's **Federal Register**?

In a separate proposal published elsewhere in the **Federal Register** today, we are also proposing to conditionally exempt hazardous waste mixed with low-level radioactive wastes (low-level mixed wastes, or LLMW) or mixed with Naturally Occurring and/or Accelerator-produced Radioactive Material (NARM mixed waste) from the storage, transportation, and disposal requirements of RCRA. Treated LLMW and NARM mixed waste would be exempt from RCRA hazardous waste transportation and disposal facility requirements if it is disposed at a low level radioactive waste disposal facility (LLRWDF) regulated by the Nuclear Regulatory Commission (NRC). In addition, we are also proposing that untreated LLMW and NARM mixed waste generated by the NRC licensees may be stored according to NRC regulations instead of RCRA hazardous waste storage regulations.

C. What Is EPA's Legal Obligation With Respect to This Proposal?

Our legal obligation for this proposal stems from EPA's fiscal year 1993 appropriation act, which required EPA to revise the mixture and derived-from rules, 40 CFR 261.3(a)(2)(iv) and 40 CFR 261.3(c)(2)(i), by October 1, 1994. (Pub. L. No. 102–389, 106 Stat. 1571). Congress made the deadline enforceable under RCRA's citizen suit provision, section 7002, 42 U.S.C. § 6972. We did not meet this deadline for revisions, and in early October 1994 several groups of waste generating and waste managing industries filed suits to enforce the deadline.

Two of the cases were consolidated and a third was dismissed with the plaintiffs being added as intervenors to the consolidated cases. *Environmental Technology Council* v. *Browner,* C.A. No. 94–2346 (TFH)(D.D.C.). The U.S. District Court for the District of Columbia entered a consent decree resolving the consolidated cases on May 3, 1993. The consent decree, as subsequently amended, required the Administrator to sign a proposal to revise the mixture and derived-from rules by November 13, 1995 and a notice of final action on the proposal by February 13, 1997. The decree reflects the parties' understanding that EPA's leading option was developing a multipathway risk assessment to establish constituent-specific, risk-based ''exit levels'' for listed hazardous wastes. It does not, however, specify what types of revisions EPA needs to propose or promulgate. On November 13, 1995, the Administrator signed the proposed Hazardous Waste Identification Rule (HWIR) to revise the mixture and derived-from rules. This proposal was published in the **Federal Register** on December 21, 1995. (60 FR 66344). It proposed a set of exemption levels for hundreds of hazardous constituents. Many of these exemption levels were based on a complex multipathway risk assessment. The notice also proposed to revise the derived-from rule to provide relief for

hazardous wastes listed because they exhibited the characteristics of ignitability, corrosivity and/or reactivity, and solicited comment on the concept of providing a separate exemption for hazardous wastes mixed with low level radioactive wastes.

We received extensive comments, many critical, on the 1995 HWIR proposal, particularly with respect to the scientific risk assessment. We continued to view risk-based exemption levels based on a multipathway risk assessment as our preferred option. We concluded that considerable work needed to be done to resolve the complex scientific and technical issues raised in the comments. We negotiated with the parties to extend the deadlines in the decree to allow us time to address these issues. On April 11, 1997, the District Court entered an order amending the consent decree in *Environmental Technology Council* v. *Browner.*

The amended decree revised the deadlines for a revision to the mixture and derived-from rules, with an October 31, 1999 deadline for the Administrator to sign a proposal, and an April 30, 2001 deadline to sign a notice taking final action. The amended decree also included 11 different provisos that we are obligated to make our best efforts to address. They require EPA to solicit comment on a number of issues related to risk assessment and to the implementation scheme we were developing for the exemption levels that the risk assessment would support. Today's rulemaking, in conjunction with the mixed waste proposal, also to be published today, fulfills our obligations under the consent decree.

Specifically, the amended consent decree required EPA to sign a notice proposing revisions to the mixture and derived-from rules in 40 CFR 261.3(a)(2(iv) and (c)(2)(i), and request comment on the 11 provisos listed in the decree. The consent decree reflected EPA's intent to further study three broad areas regarding hazardous constituents in hazardous waste and to establish a constituent-based exemption from hazardous waste regulation for low-risk wastes currently subject to RCRA subtitle C regulation. It also reflected EPA's intent to ''make best efforts'' to describe and discuss the items in the 11 provisos.

The three areas of study were: (a) Modeling of anaerobic biodegradation of hazardous constituents in the saturated zone, (b) the physical relationship between waste concentrations and leachate concentrations, and of mass limitations in leachate, and (c) the use of additional toxicity data from sources outside EPA. Seven of the 11 provisos concerned particular issues for EPA to study with respect to these three areas of study. Three provisos concerned options for implementing the exemption levels EPA expected to derive from the modeling. Finally, one proviso concerned an exemption from hazardous waste regulation for certain radioactive hazardous mixed wastes generated by nuclear power plants that are subject to regulation by the Nuclear Regulatory Commission (or states authorized to implement those regulations).

As contemplated in the consent decree, we developed a new model to analyze hazardous constituents in hazardous waste. We addressed the seven modeling-related issues listed in the provisos, either by incorporating steps in the model to produce data with respect to those issues, or by studying the issues and concluding that it was not possible to include them in a model at this time (see Sections XV to XIX). We addressed the three implementation-related provisos by developing a plan to implement a program to exempt certain waste currently regulated as hazardous waste under RCRA subtitle C from full hazardous waste regulation, based on meeting risk-based exemption levels for hazardous constituents (see Sections V to XIV). Finally, as stated above, the mixed waste provision is addressed in a separate notice of proposed rulemaking.

Despite a concerted, sustained effort, we did not succeed in developing within the consent decree time frame a risk assessment capable of generating reliable exemption levels. We concluded that we could not implement our preferred option by the October 31 deadline for proposed revisions. Moreover, we were not sure how much additional time we would need to address the remaining modeling issues. We concluded that we would better serve the public interest and better utilize our rulemaking resources by proceeding with the options that were ready for proposal rather than seeking another deadline extension for the purposes of resolving the complex technical issues presented by the risk assessment. Therefore, we decided to propose (1) Revisions to the mixture rule for wastes listed because they exhibit the characteristics of ignitability, corrosivity, and/or reactivity described in Section IV below, and (2) a set of conditional exemptions from various Subtitle C regulations (including the mixture and derived-from rules) for certain low-level radioactive wastes as described in the separate proposal published elsewhere today, including the conditional exemptions from the mixture and derived-from rules proposed here today.

D. How Does Today's Notice Relate to the 1995 HWIR Proposal?

In 1995, we published an HWIR proposal that included revisions to the mixture and derived-from rules and a discussion of exemptions similar to the HWIR exemption scenarios discussed in today's notice (60 FR 66344 (December 21, 1995)). Comments we received on the HWIR95 proposal have been invaluable in crafting today's notice, particularly in revising the risk assessment, and we will formally respond to those comments, as well as to comments on today's notice, when we promulgate a final rule. Today's notice is technically a supplement to HWIR95. However, because it has been four years since the 1995 HWIR proposal, we have written today's notice as a stand alone proposal. You do not have to read the 1995 proposal to understand today's notice.

E. What Other Regulatory Options Have Been Received From EPA Stakeholders?

In August 1999, we received a paper from the Chemical Manufacturers Association (CMA) describing five additional regulatory options, including suggested regulatory language, for revising the mixture and derived-from rules (see *Memorandum from Dorothy Kellogg, CMA to Elizabeth Cotsworth, Acting Director, Office of Solid Waste,* August 1999). CMA forwarded these options seeking regulatory relief for some specific high-volume wastes that they believe are low-risk and feel that EPA could propose to exempt with very little delay. Although we have not had time to analyze these options, we would like to present them here for others to provide their views.

Three of these options involve exempting from the hazardous waste derived-from rule: (1) Residues from the combustion of listed hazardous waste, (2) leachate from the land disposal of listed hazardous waste (that is subsequently managed in a system regulated under the Clean Water Act), and (3) sludges from the biological treatment of listed hazardous wastewaters. In each of these cases, CMA argues that the wastes are both physically and chemically dissimilar from the wastes that were originally listed. In addition, CMA notes that combustion and biological treatment can greatly reduce or eliminate organic chemicals. Under the options presented in CMA's discussion papers, each of these wastes would not be hazardous, even though they are generated from the

treatment, storage or disposal of hazardous waste, unless they exhibit one or more of the hazardous waste characteristics of 40 CFR Part 261.3.

CMA's paper does not, however, explicitly address how LDR treatment standards would apply to these residues. Especially in the case of the ash and wastewater treatment sludge, which would often result from LDR treatment, if the wastes do not meet the LDR standards, then there would be a question of whether further treatment to meet LDRs would be required.

EPA has already been considering another possible approach for addressing combustion residues, which would list these derived-from wastes under their own multi-source listing code, similar to multi-source leachate (F039). This listing would continue to regulate these wastes as hazardous, but application of other requirements could be tailored to fit the physical and chemical properties of these wastes. EPA is developing an Advance Notice of Proposed Rule Making (ANPRM) that would discuss the idea of a new listing for combustion residues. More information on this ANPRM (SAN No. 4093) can be found in the most recent agenda of regulatory and deregulatory actions (64 FR 21987 (April 26, 1999)).

In their materials, CMA has forwarded specific changes to regulatory language currently in effect and found in the Code of Federal Regulations (CFR). EPA has not evaluated this language and presents it here to enhance public dialogue on these ideas. CMA suggests that we modify 40 CFR 261.3(c)(2)(ii) and add the following language:

''[1] Wastes derived from burning any listed hazardous waste in a permitted or interim status hazardous waste combustion device; [2] Leachate derived from landfills or land treatment units containing listed hazardous waste, which is managed in a wastewater treatment system the discharge of which is subject to regulation under either section 402 or section 307(b) of the Clean Water Act (including wastewater at facilities which have eliminated the discharge of wastewater); [3] Wastes derived from the aggressive biological treatment of listed hazardous wastewaters in a wastewater treatment systems the discharge of which is subject to regulation under either section 402 or section 307(b) of the Clean Water Act (including wastewater at facilities which have eliminated the discharge of wastewater).''

The other two options presented in the paper involve specific wastes that result from the mixture of hazardous wastes with solid wastes. One option involves an expansion of the current ''headworks'' exemption in 40 CFR 261.3(a)(2)(iv)(A) and (B). The headworks exemption exempts from the mixture rule wastewaters containing small quantities of particular F-listed solvents, based on the mass-balance flow of these solvents through the headworks of industrial wastewater treatment systems. CMA's options paper requests that this exemption be amended in three ways.

First, CMA's suggested revision would allow direct monitoring of the actual concentration of spent solvents in untreated wastewater to demonstrate compliance. The current requirement is to perform a weekly mass balance of the solvents entering the system. Losses due to volatilization must be counted in the mass balance determination under the current system. We note that CMA's suggested wastewater monitoring would provide accurate data at the point the wastewater enters the treatment system, but the losses due to volatilization would not be counted in this approach.

Second, under the revised headworks exemption, benzene, 2-ethoxyethanol, 2-nitropropane, and 1,1,2-trichloroethane would be incorporated into the list of chemicals. These four chemicals were added to the 261.31 list of spent solvents in 1986 but the exemption does not currently include these chemicals.

Third, under the revised headworks exemption, multi-source leachate (F039) derived solely from the disposal of the spent solvents listed in 40 CFR 261.31 would be eligible for the exemption.

Again, CMA has forwarded specific changes to regulatory language currently in effect and found in the Code of Federal Regulations (CFR). EPA has not evaluated this language and presents it here to enhance public dialogue on these ideas. CMA suggests that we modify 40 CFR 261.3(a)(2)(iv)(A) and (B) to read as follows:

''40 CFR 261.3(a)(2)(iv)(A). One or more of the following solvents listed in § 261.31—carbon tetrachloride, tetrachloroethylene, trichloroethylene [add solvents that meet the standards to be included in this paragraph], including multi-source leachate derived from the disposal of these solvents and no other listed hazardous wastes—Provided, That either the actual concentration of these solvents or the maximum total weekly usage of these solvents (other than the amounts that can be demonstrated not to be discharged to wastewater) divided by the average weekly flow of wastewater into the headworks of the facility's wastewater treatment or pretreatment system does not exceed 1 part per million; or * * *

40 CFR 261.3(a)(2)(iv)(B). One or more of the following solvents listed in § 261.31—methylene chloride, 1,1,1-trichloroethane, chlorobenzene, o-dichlorobenzene, cresols, cresylic acid, nitrobenzene, toluene, methyl ethyl ketone, carbon disulfide, isobutanol, pyridine, spent chlorofluorocarbon solvents [add solvents that meet the standards to be included in this paragraph], including multi-source leachate derived from the disposal of these solvents and no other listed hazardous wastes—Provided, That either the actual concentration of these solvents or the maximum total weekly usage of these solvents (other than the amounts that can be demonstrated not to be discharged to wastewater) divided by the average weekly flow of wastewater into the headworks of the facility's wastewater treatment or pretreatment system does not exceed [25] part per million; or * * *''

These modifications add 4 chemicals to either paragraph (A) or (B), include leachate derived from the disposal of these solvents and no other listed hazardous waste and allow for the demonstration by direct measurement that concentrations do not exceed the specified levels. Note the 25 ppm threshold specified in 40 CFR 261.3(a)(2)(iv)(B) is the threshold within current regulations, and we do not believe it was CMA's intention to alter this level to 1 ppm, the level stated in their materials.

The other regulatory option involving hazardous waste mixtures would be an expansion of a current exemption for ''de minimis'' losses that result from the manufacture of commercial chemical product. The current exemption, found in 40 CFR 261.3(a)(2)(iv)(D), exempts from the mixture rule small losses of a commercial chemical product that can result from normal handling of the chemicals during the manufacturing process. The existing exemption applies to some but not all hazardous wastes listed in 40 CFR 261.33 (see 46 FR 56586). CMA's suggested expansion of this option would also exempt small losses from the normal handling of all listed hazardous wastes (instead of just the handling of commercial chemical products). One rationale for the current ''de minimis'' exemption is that a facility has little economic incentive to allow spills, leaks or other losses of commercial products. With respect to wastes, CMA believes that tank and container and air emission management standards of 40 CFR Parts 264 and 265, Subparts I, J, BB, and CC serve to encourage safe management of these wastes.

Specific changes forwarded by CMA would modify 40 CFR 261.3(a)(2)(iv)(D). EPA has not evaluated this language and presents it here to enhance public dialogue on these suggestions. Their language reads as follows:

''40 CFR 261.3(a)(2)(iv)(D). One or more hazardous wastes listed in Subpart D, arising from de minimis losses of these materials from manufacturing and related operations in which these materials are generated. For purposes of paragraph (a)(2)(iv)(D), ''*de minimis*'' losses include those from normal material handling operations (e.g., spills from the unloading or transfer of materials from bins or other containers, leaks from pipes, valves or other devices used to transfer materials); minor leaks of process equipment, storage tanks or containers; leaks from well maintained pump packings and seals; sample purging; relief device discharges; discharges from safety showers and rinsing and cleaning of personal safety equipment; and rinsate from empty containers or from containers that are rendered empty by that rinsing; or''

Note that the phrase ''One or more hazardous wastes listed in Subpart D'' replaces the more narrow eligibility contained in the current regulation as ''a discarded commercial chemical product, or chemical intermediate listed in 261.33.'' Also note the origin of these wastes has been made broader by the inclusion of the term ''generated'' replacing the phrase ''used as raw materials or are produced in the manufacturing process.''

We request comment on the merits and drawbacks of all these possible revisions to the mixture and derived-from rules and on how LDR standards should apply. We also request any data that may help us to further evaluate (a) the potential risks to human health and the environment, (b) any special or unique technical considerations, and (c) the economic effects of each of the possible revisions.

Retaining the Mixture and Derived-From Rules

III. Why Is EPA Proposing To Retain the Mixture and Derived-From Rules?

A. What Are the Mixture and Derived-From Rules?

The mixture and derived-from rules are a part of the RCRA regulations that define which wastes are considered to be hazardous and therefore subject to RCRA Subtitle C regulations. The mixture rule discussed in today's notice refer specifically to 40 CFR 261.3(a)(2)(iii) and (iv). Under the mixture rule, a solid waste becomes regulated as a hazardous waste if it is mixed with one or more listed hazardous wastes The derived-from rule discussed in today's notice refers specifically to 40 CFR 261.3(c)(2)(i). Under the derived-from rule, any solid waste generated from the treatment, storage, or disposal of a hazardous waste remains regulated as a hazardous waste. These derived-from wastes include wastes such as sludges, spill residues, ash, emission control dust, and leachate.

B. What Is the Legal History of the Mixture and Derived-From Rules?

EPA promulgated the mixture and derived-from rules in 1980 as part of the comprehensive ''cradle to grave'' requirements for managing hazardous waste. 45 FR 33066 (May 19, 1980). Numerous industries that generate hazardous wastes challenged the 1980 mixture and derived-from rules in *Shell Oil Co.* v. *EPA*, 950 F. 2d 741 (D.C. Cir. 1991). In December 1991 the D.C. Circuit Court of Appeals vacated the rules because they had been promulgated without adequate notice and opportunity to comment. The court, however, suggested that EPA might want to consider reinstating the rules pending full notice and comment in order to ensure continued protection of human health and the environment.

In response to this decision, we promulgated an emergency rule reinstating the mixture and derived-from rules as interim final rules without providing notice and opportunity to comment. 57 FR 7628 (March 3, 1992). We also promulgated a ''sunset provision'' which provided that the mixture and derived-from rules would remain in effect only until April 28, 1993. Shortly after, we published a proposal containing several options for revising the mixture and derived-from rules. See 57 FR 21450 (May 20, 1992). The May 1992 proposal and the time pressure created by the ''sunset provision'' generated significant controversy. In response, Congress included in EPA's FY1993 appropriation several provisions addressing the mixture and derived-from rules. Pub. L. No. 102–389, 106 Stat. 1571. First, Congress nullified the sunset provision by providing that EPA could not promulgate any revisions to the rules before October 1, 1993, and by providing that the reinstated regulations could not be ''terminated or withdrawn'' until revisions took effect. However, to ensure that we could not postpone the issue of revisions indefinitely, Congress also established a deadline of October 1, 1994 for the promulgation of revisions to the mixture and derived-from rules. Congress made this deadline enforceable under RCRA's citizen suit provision, section 7002.

On October 30, 1992, we published two notices, one removing the sunset provision, and the other withdrawing the May 1992 proposal. (See 57 FR 49278, 49280). We had received many comments criticizing the May 1992 proposal. The criticisms were due, in a large part, to the very short schedule imposed on the regulation development process itself. Commenters also feared that the proposal would result in a ''patchwork'' of differing State programs because some states might not adopt the revisions. This fear was based on the belief that States would react in a negative manner to the proposal and refuse to incorporate it into their programs if finalized. Finally, many commenters also argued that the risk assessment used to support the proposed exemption levels failed to provide adequate protection of human health and the environment because it evaluated only the risks of human consumption of contaminated groundwater and ignored other pathways that could pose greater risks. Based on these concerns, and based on EPA's desire to work through the individual elements of the proposal more carefully, we withdrew the proposal.

Subsequently, a group of waste generating industries challenged the March 1992 action that reinstated the mixture and derived-from rules without change. *Mobil Oil Corp.* v. *EPA*, 35 F.3d 579 (D.C. Cir. 1994). The court rejected this challenge, adopting our argument that the appropriations act made the challenge moot because it prevented both us and the courts from terminating or withdrawing the interim rules before we revised them, even if we failed to meet the statutory deadline for the revisions.

We did not meet Congress' October 1, 1994 deadline for revising the mixture and derived-from rules. In early October 1994 several groups of waste generating and waste managing industries filed citizen suits to enforce the October 1, 1994 deadline for revising the mixture and derived-from rules. The U.S. District Court for the District of Columbia entered a consent decree resolving the consolidated cases on May 3, 1993. *Environmental Technology Council* v. *Browner*, C.A. No. 94–2119 (TFH) (D.D.C. 1994). The consent decree originally required the Administrator to sign a proposal to amend the mixture and derived-from rules by November 13, 1995 and a notice of final rulemaking by December 15, 1996, and specified that the deadlines in the appropriations act do not apply to any rule revising the

separate regulations that establish jurisdiction over media contaminated with hazardous wastes. On November 13, 1995, the Administrator signed the proposed Hazardous Waste Identification Rule to revise the mixture and derived-from rules, which was published in the **Federal Register** on December 21, 1995. (60 FR 66344).

We received extensive comments, many critical, on the 1995 proposal, particularly with respect to the scientific risk assessment supporting the proposed revisions to the mixture and derived-from rules. As a result of the comments, we concluded that considerable work needed to be done to resolve complex scientific and technical issues raised by the risk assessment and the comments received. On April 11, 1997, the District Court entered an order amending the consent decree in *Environmental Technology Council* v. *Browner.* The amended decree provided us with additional time to perform further scientific risk assessment work and requires us to address specific issues and options for revising the mixture and derived-from rules. The amended decree calls for a notice of proposed rulemaking to revise the mixture and derived-from rules, with an October 31, 1999 deadline for the Administrator to sign a proposal, and an April 30, 2001 deadline to sign a notice of final rulemaking. Until this rule is promulgated, the mixture and derived-from rules are considered to remain in effect on an ''emergency basis.''

C. Why Is EPA Proposing To Retain the Mixture and Derived-From Rules?

The mixture and derived-from rules are necessary to regulate hazardous wastes in a way that protects human health and the environment. Mixtures and residuals of hazardous waste represent a large and varied universe. Many hazardous wastes continue to be toxic after they have been mixed with other waste or have been treated. As explained below, without the mixture and derived-from rules, such wastes could easily escape coverage of RCRA Subtitle C regulations, while nevertheless posing risks to human health and the environment.

We believe that without the mixture and derived-from rules, some generators would alter their waste to the point it no longer meets the listing description without detoxifying, immobilizing, or otherwise actually treating the waste. For example, without a ''mixture'' rule, generators of hazardous wastes could escape regulatory requirements by mixing listed hazardous wastes with other hazardous wastes or nonhazardous solid wastes to create a ''new'' waste that arguably no longer meets the listing description, but continues to pose a serious hazard. Similarly, without a ''derived-from'' rule, hazardous waste generators could potentially evade regulation by minimally processing or managing a hazardous waste and claiming that the resulting residue is no longer the listed waste, despite the continued hazards of the residue. (See 57 FR 7628). It is therefore necessary for protection of human health and the environmental to capture mixtures and derivatives of listed hazardous waste in the universe of regulated hazardous wastes. A hazardous waste regulatory system that allowed hazardous waste to leave the system as soon as it was modified to any degree by being mixed or marginally treated would be ineffective and unworkable. Such a system could act as a disincentive to adequately treat, store and dispose of listed hazardous waste.

We know that mixtures and residuals of hazardous waste can be hazardous based on our experience in identifying and regulating hazardous waste. For example, during the listing process, we review data on specific waste streams generated from a number of industrial processes to determine whether these wastes would pose hazards to human health or the environment if mismanaged. Through the listing process, we have determined risks arising from the disposal of waste mixtures and derived-from wastes. Leachate generated from hazardous wastes is a particularly good example of residuals of hazardous wastes that contain toxic chemicals that can endanger environmental or human receptors. Our risk analyses have shown that multi-source leachate derived from hazardous waste landfills can contain very high concentrations of toxic organic compounds and metals. (Preliminary Data Summary for the Hazardous Waste Treatment Industry, EPA/OW, 1989). Other derived-from wastes that, because of their treatment process, can result in higher concentrations of chemicals (especially metals) than their parent wastes include wastewater treatment sludge and combustor ash. As a result of either wastewater treatment or combustion, the wastes would have their volumes greatly reduced, but could still contain the same amount of inorganic chemicals, thus resulting in a higher concentration of chemicals.

Our experience with delisting petitions also supports the need to regulate as hazardous mixtures and residuals of listed hazardous waste in order to protect human health and the environment. Generators can petition us under 40 CFR 260.22 to exclude a waste produced at a particular facility from the definition of hazardous waste. Such petitions must demonstrate that the waste does not meet any of the criteria for which it was listed nor has other attributes that might result in the waste being hazardous. As of March 27, 1995, we have denied or dismissed 139 of 809 (17%) of delisting petitions received. This estimate does not include 543 petitions (67% of the total) that were withdrawn (311), mooted (198) or referred to the State authority (34). The chief reason for denying or dismissing most of the 139 delisting petitions was failure by the petitioner to supply adequate information. However, in at least 13 cases, we denied delisting petitions for mixtures or residuals of listed waste because risk analyses indicated that the toxicity and leaching potential of hazardous chemicals in those wastes posed unacceptable risk to human health (see *Disposition of Delisting Petitions for Derived-From/ Mixture Wastes,* U.S. EPA memorandum, 1992 and *Analysis of the Delisting Petition Data Management System*, U.S. EPA, September 1998). We have also identified damage cases associated with mixture and derived-from wastes. For example, there are Superfund sites that contain mixture and derived-from wastes (See 50 FR 658). In many cases, determining when the environmental damage occurs on a site is difficult, but we have identified at least nine sites that involve the mismanagement of mixture and derived-from wastes. (see ''Releases of Hazardous Constituents Associated with Mixture and Derived-from Wastes,'' EPA 1999). These waste types are also associated with RCRA corrective actions where high concentrations of hazardous chemicals were found in the vicinity of units that contained a listed waste. (*Data on Mixture and Derived-from Wastes from Closures and Corrective Action at Hazardous Waste Management Facilities,* EPA, 1992).

In addition, through the development of the LDR program, we have considered the appropriateness and effectiveness of various hazardous waste treatment technologies. Treatments specified within the LDR regulations, promulgated under 40 CFR 268, are required for hazardous waste to be land disposed. However, technology-based treatment standards do not always equate with low risk. In addition, treatment that is not performed properly or is not fully optimized may result in residues that present some risk. Further discussion and examples of LDR treatment are presented in a background

document entitled *Memorandum to the Docket from Larry Rosengrant Regarding Section 3004(m) of the Hazardous and Solid Waste Amendments,* U.S. EPA January 21, 1992. Since treatment standards are based on the limits of technology, residuals can still pose sufficient risk to warrant continued regulation under RCRA Subtitle C.

D. Does EPA Have the Legal Authority To Retain the Mixture and Derived-From Rules?

We have had, and we continue to have the statutory and regulatory authority to promulgate the mixture and derived-from rules. The mixture and derived-from rules, particularly with the revisions proposed today, ensure that hazardous wastes that are mixed with other wastes or treated in some fashion do not escape regulation as long as they are reasonably likely to threaten human health and the environment. These rules retain jurisdiction over listed hazardous wastes and clarify that such wastes do not automatically exit the Subtitle C system when they are mixed or treated, however minimally.

The mixture and derived-from rules are valid exercises of our authority to list hazardous waste under section 3001 of RCRA. We have consistently interpreted section 3001(a) as providing EPA with flexibility in deciding whether to list or identify a waste as hazardous, that is to consider the need for regulation. Specifically, section 3001 requires that EPA, in determining whether to list a waste as hazardous waste, or to otherwise identify a waste as hazardous waste, decided whether a waste ''should be subject to the requirements of Subtitle C.'' Hence, section 3001 authorizes us to determine when Subtitle C regulation is appropriate. The statute directs EPA to regulate hazardous waste generators (section 3002(a)), hazardous waste transporters (section 3003(a)), and hazardous waste treatment, storage, and disposal facilities (section 3004(a)) ''as necessary to protect human health and the environment.'' By extension, the decision of when waste should be subject to the regulatory requirements of Subtitle C is essentially a question of whether regulatory controls promulgated under sections 3002–3004 are necessary to protect human health and the environment. We have therefore consistently interpreted section 3001 to give us broad flexibility in fashioning criteria for hazardous wastes to enter or exit the Subtitle C regulatory system. See, *Military Toxics Project* v. *EPA,* 146 F.3d 948, 958 (D.C. Cir. 1998).

EPA's 1980 criteria authorize the listing of classes of hazardous wastes when we have reason to believe that wastes in the class are typically or frequently hazardous. See 40 CFR 261.11(b). As discussed Section III.C. above, EPA has ample reasons for classifying mixtures and residuals of listed hazardous waste as hazardous wastes.

In addition to providing the context in which the determination of whether a waste ''should be subject to the requirements of Subtitle C,'' sections 3002–3004 allow us to impose requirements on waste handlers until wastes have ''cease[d] to pose a hazard to the public.'' *Shell Oil Co.* v. *EPA,* 959 F.2d 741, 754 (D.C. Cir. 1991). See also *Chemical Manufacturers Assoc.* v. *EPA,* 959 F.2d 158, 162–65 (D.C. Cir. 1990) (EPA may regulate the disposal of nonhazardous wastes in a hazardous waste impoundment under section 3004) and *Chemical Waste Management, Inc.* v. *EPA,* 976 F.2d 2, 8, 13–14 (D.C. Cir. 1992) (EPA may require further treatment of wastes under section 3004 even though they cease to exhibit a hazardous characteristic).

Proposed Revisions to 40 CFR 261.3

IV. How and Why Is EPA Proposing To Revise the Hazardous Waste Identification Regulations for Mixtures and Derived-From Wastes?

A. How and Why Is EPA Proposing To Revise the Hazardous Waste Identification Regulations for Wastes That Were Listed Solely for Ignitability, Corrosivity and/or Reactivity?

There are 29 waste codes within the RCRA program listed solely for ignitability, corrosivity, and/or reactivity characteristics. Currently, 40 CFR 261.3(a)(2)(iii) specifies that a *mixture* of these wastes and a solid waste is no longer a hazardous waste if the mixture does not exhibit a hazardous characteristic. These mixtures must still meet the LDR requirements of 40 CFR 268.40.

We believe that wastes listed solely because they exhibit the ignitability, corrosivity and/or reactivity characteristics should all be treated identically, whether they are mixtures, residuals, or wastes meeting the original listing description as generated. For example, ash resulting from the combustion of an ignitable listed waste would no longer exhibit the characteristic of ignitability. Under the current derived-from rule, this ash would not be exempt, however if it were a ''mixture'' rather than a treatment residual, it would be exempt under the current mixture rule. Another example are nitroglycerine patches, which when used for medical purposes are not reactive even at the point they are manufactured, but are regulated as P081 when discarded. Thus, today's proposed revision would expand this exemption which is currently in the mixture rule only, so that all these materials would be exempt from hazardous waste regulation if they are de-characterized and meet the appropriate LDR treatment standards, including treatment for all underlying hazardous constituents (as defined in 40 CFR 268.3(i)). Table 1 presents the 29 wastes codes and the characteristic(s) that are the basis for their listing.

TABLE 1.—WASTES LISTED FOR IGNITABILITY, CORROSIVITY, AND/OR REACTIVITY

	Waste code	Description	Hazard code
1	F003	Spent xylene and other non-halogenated solvents	(I)
2	K044	Wastewater treatment sludges from the manufacturing and processing of explosives	(R)
3	K045	Spent carbon from the treatment of wastewater containing explosives	(R)
4	K047	Pink/red water from TNT operations	(R)
5	P009	Ammonium Picrate	(R)
6	P081	Nitroglycerine	(R)
7	P112	Tetranitromethane	(R)

TABLE 1.—WASTES LISTED FOR IGNITABILITY, CORROSIVITY, AND/OR REACTIVITY—Continued

	Waste code	Description	Hazard code
8	U001	Acetaldehyde	(I)
9	U002	Acetone	(I)
10	U008	Acrylic Acid	(I)
11	U031	n-Butyl alcohol	(I)
12	U020	Benzenesulfonyl chloride	(C, R)
13	U055	Cumene	(I)
14	U056	Cyclohexane	(I)
15	U057	Cyclohexanone	(I)
16	U092	Dimethylamine	(I)
17	U096	Cumene Hydroperoxide	(R)
18	U110	Di-n-propylamine	(I)
19	U112	Ethyl Acetate	(I)
20	U113	Ethyl Acrylate	(I)
21	U117	Ethyl Ether	(I)
22	U124	Furan	(I)
23	U125	Furfural	(I)
24	U154	Methanol	(I)
25	U161	Methyl isobutyl ketone	(I)
26	U186	1,3 Pentadiene	(I)
27	U189	Sulfur phosphide	(R)
28	U213	Tetrahydrofuran	(I)
29	U239	Xylene	(I)

I=ignitability, C=corrosivity, R=reactivity

As explained in Section XXI, the majority of the waste which would be eligible for this exemption would be F003 (spent xylene and other non-halogenated solvents). However, the full listing description for F003 in 40 CFR 261.31 includes the following statement: ''and all spent solvent mixtures/blends containing, before use, one or more of the above non-halogenated solvents, and, a total of ten percent or more (by volume) of one or more of those solvents listed in F001, F002, F004, and F005 * * *'' Although F003 is listed solely for ignitability, its listing description includes references to solvents that were listed for toxicity as well. This is one of the reasons that LDR standards reference a composite list of chemicals that must be treated for F001, F002, F003, F004 and F005. We therefore request comment on whether to allow F003 to be eligible for this proposed exemption.

B. How Is EPA Proposing To Revise The Mixture and Derived-From Rules for Mixed Waste?

In the revisions to 40 CFR Part 261.3 that we are proposing today, we also include a conditional exemption for mixed waste from the mixture and derived-from rules, provided the mixed waste is handled in accordance with 40 CFR Part 266, Subpart N.

The proposed regulatory language in 40 CFR Part 266, Subpart N, which we are including in a separate **Federal Register** notice published elsewhere today conditionally exempts hazardous waste mixed with low-level radioactive wastes (low-level mixed wastes/LLMW), or mixed with Naturally Occurring and/or Accelerator-produced Radioactive Material (NARM mixed waste) from the storage, treatment in tank, transportation, and disposal requirements of RCRA. Nuclear Regulatory Commission (NRC) or its Agreement State licensed LLMW generators can store, or treat LLMW in storage tanks without RCRA Subtitle C permits if all exemption conditions are met. Treated LLMW or NARM mixed waste could be disposed at a low level radioactive waste disposal facility (LLRWDF) regulated by the NRC or its Agreement State if all exemption conditions are met. The rationale for conditionally exempting LLMW from the mixture and derived-from rules is the same as that for creating the conditional exemption from the RCRA regulatory definition of hazardous waste for LLMW. We incorporate by reference the notice of proposed rulemaking for the LLMW conditional exemption (EPA Docket Number F–1999–ML2P–FFFFF). We request comment on whether to conditionally exempt low level mixed wastes from the mixture and derived-from rules.

HWIR Exemption Options

V. Why Is EPA Developing a Chemical-Based HWIR Exemption for Listed Hazardous Waste (Including Both Mixtures and Derived-From Waste)?

A. What Issue Would the HWIR Exemption Address?

The HWIR exemption would refine the regulation of hazardous wastes by improving identification of lower risk hazardous wastes, while ensuring that the health of our nation's citizens and environment is not compromised. Wastes are hazardous and subject to RCRA Subtitle C regulations if they exhibit certain characteristics (''characteristic wastes'') or if they have been placed on certain lists by EPA (''listed wastes'').

Once a waste is identified as a listed hazardous waste, it remains regulated as hazardous, even if it has been treated to remove all hazardous chemicals, unless the wastes are formally delisted. Delisting under 40 CFR 260.22 requires a formal rulemaking process under the Administrative Procedures Act (APA). Delistings are waste stream specific, with close government review of sampling procedures, analytical test results, and the accompanying quality assurance and quality control (QA/QC) data. This process has the advantage of tailoring the delisting determination to the specific waste, but it is also resource intensive and time consuming for both the petitioner and the government. Such costs could discourage a generator from

exploring the use of pollution prevention and new waste treatment technologies to detoxify his waste. By offering a self-implementing alternative, the HWIR exemption would exempt low-risk wastes more quickly and at less cost than the current delisting process.

B. How Would the HWIR Exemption Affect the Regulation of Hazardous Waste?

Under this approach, wastes that have been designated as listed hazardous wastes under Subpart D of 40 CFR Part 261 (or are mixed with, derived from, or contain listed hazardous wastes) would no longer be subject to the full ''cradle to grave'' RCRA Subtitle C hazardous waste management requirements, if the chemicals of concern in the wastes are below risk-based exemption levels. The waste would instead be managed under RCRA Subtitle D nonhazardous waste management requirements, which better match the risks posed by this low-risk waste. The HWIR approach would be self-implementing, and therefore less burdensome both to the generator and the overseeing agency than the current delisting process.

C. How Would the Exemption Continue To Ensure Protection of Human Health and the Environment?

HWIR would continue to ensure protection of human health and the environment by establishing numerical risk levels that are based on a multi-media approach to environmental protection. The risk models that would underlie the exemption levels in the HWIR exemption predict the potential release of hazardous chemicals from waste management units to the air, land, surface water, and groundwater. If wastes contain these chemicals at concentrations greater than these levels, they would remain regulated as hazardous under RCRA Subtitle C. On the other hand, those wastes that no longer contain these chemicals or that can be demonstrated to contain these chemicals below these levels, would no longer be considered hazardous under RCRA Subtitle C, but would still be subject to State nonhazardous waste regulations. The HWIR exemption would also include testing and documentation requirements to ensure that the exemption levels have been and continue to be met.

VI. What Options Is EPA Developing for the HWIR Exemption?

We are developing two options for the HWIR exemption: (1) The ''generic'' HWIR exemption, and (2) the ''landfill-only'' HWIR exemption. As discussed in Section XVII of this preamble, we are not proposing the HWIR exemption because of technical difficulties in developing chemical-specific exemption levels from the model. Before we would promulgate an HWIR exemption, we would first publish an HWIR proposal that would include specific exemption levels and give the public an opportunity to comment. Therefore, our discussion consists of a ''framework'' for the two HWIR exemption options. In this discussion, ''you'' refers to the person who would wish to claim an exemption for a waste under these options.

A. What Is the Generic HWIR Exemption option?

Under the generic HWIR exemption option, your listed hazardous waste would no longer be hazardous once the risk-based exemption levels have been satisfied, and you fulfill the conditions and requirements discussed in Section IX of this preamble. The exemption levels would be listed in a new appendix to 40 CFR Part 261 (Appendix X), found in Table 2, in Section XIV of this preamble. You would have to continue to meet specific waste testing requirements to ensure that the waste remains below the HWIR exemption levels.

This option is based on the premise that the HWIR exemption levels would be protective in all reasonable waste disposal scenarios. Therefore, there would be no limits to where an HWIR waste could be disposed under this option, except for existing State requirements that apply to all nonhazardous industrial wastes. A discussion of the risk assessment model supporting this option can be found in Sections XV through XIX of today's preamble.

B. What Is the Landfill-Only HWIR Exemption?

Under the landfill-only HWIR exemption, your waste would have to meet a different set of HWIR exemption levels, found in Table 2, in Section XIV of this preamble, and you would be required to dispose of the waste in a landfill. A landfill is a land-based unit where non-liquid wastes are placed for permanent disposal, and is not a land application unit (where wastes are incorporated into the soil). This landfill would not need to be a hazardous waste landfill, but nonhazardous landfills are still regulated under existing State requirements, which would help ensure that it is protective of human health and the environment. This landfill disposal requirement is in addition to the other requirements described under the generic HWIR exemption option.

In addition, under the landfill-only exemption, you would also be required to fulfill waste tracking requirements to ensure that the waste does arrive at a landfill, and until the waste is disposed, you would not be allowed to place it on the land. We are concerned about the temporary placement of these wastes in waste piles or other such intermediate land-based destinations, because exemption levels for the landfill-only option (unlike the levels for the generic option) would not consider such risks. See Section XII of this preamble for discussion of these additional conditions and requirements.

We believe that restricting wastes to landfills and customizing the exemption levels to that unit focuses the HWIR exemption on the lowest-risk and most likely disposal scenario for non-liquids. Management in a landfill helps reduce air release and overland transport of hazardous chemicals. This option could allow for less conservative exemption levels, thus reducing regulatory costs while continuing to protect human health and the environment.

C. What Implementation Options Are in Both the 1995 HWIR Proposal and Today's Notice?

In our 1995 HWIR proposal, we developed a number of options for exempting low risk wastes from RCRA Subtitle C hazardous waste regulation. Under a proposed ''base national option,'' generators would be required to demonstrate that constituent concentrations within a waste did not exceed risk-based HWIR exemption levels. Conceptually, the base national option from 1995 is the same as today's generic option discussed in Section VI.A of this preamble. We also proposed several ''contingent management'' options, under which generators were required to meet alternate exemption levels, provided that they met additional waste management requirements. The landfill-only option discussed in Section VI.B of this preamble is similar to one of the contingent management options proposed in 1995.

When we developed today's notice, we considered all of the options discussed or proposed in 1995, plus an additional contingent management option that would require waste to be stabilized and then disposed in a landfill. (see *Evaluation of Contingent Management Options,* U.S. EPA, 1999). One of the most pervasive comments on the 1995 HWIR proposal was related to the number and complexity of alternatives, which made it difficult for readers to understand and comment on the proposal. We have decided to

develop only the two options we have deemed most viable: the base national option and the contingent management national option 1 (disposal in a landfill). As discussed above, these two options are called the generic HWIR option and the landfill-only HWIR option.

The 1999 HWIR options differ from their 1995 counterparts. The biggest changes are to the risk assessment we are developing to support the options. Instead of modeling each exposure pathway separately as we did in 1995, the current version of the model takes into account simultaneous exposures via multiple pathways. See Sections XV through XIX of this preamble for a discussion of the current version of the model. In the 1995 HWIR proposal we included more than 350 exemption levels. About half of these levels were based on risk modeling, while the other have were based on an extrapolation methodology that we have since discarded. As explained in Section XVII, today's discussion does not include any specific exemption levels because of technical difficulties in the risk modeling. Instead, we discuss the framework of the exemption and ask for comment on the modeling approach. Before we would promulgate an HWIR exemption, we would first publish an HWIR proposal that would include specific exemption levels and give the public an opportunity to comment.

In addition to modeling changes, we have also revised the discussion of some of the implementation requirements. We have scaled back the testing requirements so that facilities would not have to document why chemicals would not be in their waste (essentially proving a negative). Instead, under today's options, facilities would only have to test for chemicals ''reasonably expected'' to be in their waste; the guidelines for determining what chemicals we would ''reasonably expect'' to be in a waste are discussed in Section IX of this preamble. Also, for the generic option, we have developed three categories of wastes (liquids, semi-solids, and solids) rather than the two proposed in 1995 (wastewaters and nonwastewaters). These categories are discussed in more detail in Section XIX.C. Finally, for the landfill-only option, we would require tracking requirements to ensure that the waste arrives at its intended destination. These requirements are discussed in Section XII.B.

D. Why Did We Decide Not To Go Forward With Two of the National Contingent Management Approaches Discussed in the 1995 HWIR Proposal?

The 1995 HWIR options included three approaches that required a generator to meet national exemption levels. After carefully evaluating these options and reviewing the input we received from our stakeholders, we determined that, except for the landfill-only national contingent management option (analogous to the first national contingent management option from 1995), it would not be feasible and/or desirable to develop and implement the other approaches at this time.

Under the second national contingent management option for 1995 HWIR proposal, we considered establishing exemption levels for each type of waste management unit: landfill, waste pile, land application unit, tank, and surface impoundment. Upon further review, however, we determined that setting exemption levels for waste piles, land application units, tanks or surface impoundments was not a desirable option for several reasons.

First, waste piles and tanks are intermediate disposal destinations. It is not appropriate to exempt wastes based on exposures from just these units and no others, since the final disposition of the waste is most important for determining long-term risk. Second, we found in 1995 that the land application unit drove most of the non-liquid exemption levels and therefore separate land application unit levels would be no different from levels established for the generic option. Similarly, a surface impoundment option would be expected to be similar to levels for liquids established under the generic option, and we do not believe that separate exemption levels are warranted. Given that the generic option has fewer requirements and similar exemption levels, we decided a contingent management option for land application units and surface impoundments would add unnecessary complexity to the rule.

Under the third national contingent management option, we considered setting exemption levels for waste management units with specific design or operating controls that would allow for less conservative exemption levels. Although specific public comment on the national contingent management options was limited, representatives from industry indicated a support for options that allowed the consideration of site-specific factors. Therefore, in addition to evaluating the approach of developing separate exemption levels for each type of waste management unit, we considered developing exemption levels based upon engineering controls in place at certain units.

However, when we evaluated the unit control option, we found it difficult to quantitatively attribute a set of risk protection levels to specific engineering and management controls, especially over a long period of time. Also, in order to enforce such an option, we would need to make complex judgements regarding whether the required unit controls were being used correctly. Such determinations would be more appropriately made under the oversight of a permitting authority, rather than as a condition of a self-implementing exemption under HWIR.

E. Why Did We Decide Not To Go Forward With the State Contingent Management Approaches Discussed in the 1995 HWIR proposal?

In 1995, we proposed that qualified States would be allowed to manage listed waste in their nonhazardous waste management programs under certain conditions. We included three different State-based approaches. These three approaches differed in terms of (1) the risk-based criteria (10^{-5} versus 10^{-4} cancer risk, for example) that would be used to identify the set of wastes that could be managed under an approved State program; (2) the type of State program review that we would conduct to identify qualified State programs (qualitative and/or quantitative); and (3) the breadth of the State program that we would review and qualify. For example, we could have reviewed the entire State nonhazardous program, or only that portion related to the HWIR exemption.

As we considered the above State program approaches to contingent management, we recognized that State industrial nonhazardous waste programs have improved significantly since the early days of the RCRA Subtitle C hazardous waste program. A well-developed State program could offer a continuum of management for waste of varying risks and allow more local judgements and ongoing oversight of HWIR exemptions. Waste generators have also expressed support for State program approaches to contingent management, because site-specific or regional specific parameters could be considered to a larger extent in State risk assessments. However, after further consideration of the State program options, as well as review of the input we received from our stakeholders, we decided that the implementation of these options would be difficult.

Although the States recognize that relying upon State programs could be a

preferable alternative for the regulated community than a national approach (in terms of less conservative exemption levels for example), they expressed concern about resource implications, should they be required to independently develop exemption criteria. The States would have to perform risk assessments, which are resource-intensive and require specialized expertise. From an implementation perspective, some States would prefer for EPA to develop exemption levels for the States to implement and enforce within their Subtitle D versus Subtitle C programs. (see *Overview: State-Based Contingent Management Case Study Project, Discussion Draft for April 1–2, 1998 Joint ASTSWMO Task Force Meeting,* March 9, 1998).

Furthermore, the transfer of jurisdiction over HWIR-exempt wastes from the Federal to the State governments would entail some type of EPA review of the quality of State Subtitle D programs. One State association indicated it would be inappropriate for EPA to evaluate State Subtitle D programs as part of authorizing states to use the contingent management options.

Finally, State program approaches would result in a variety of disposal standards across the States. States and the regulated community would have to devote additional resources to ensure that waste streams generated and exiting under contingent management standards in neighboring States meet applicable transportation and disposal standards in the receiving States. A representative of the waste management industry expressed concern over the interstate transport ramifications of these approaches. For these reasons, we have decided not to pursue a State contingent management implementation option.

F. What Other HWIR Implementation Option Has EPA Considered?

We also considered another contingent management option which would establish HWIR exemption levels for stabilized wastes when managed in a landfill. This approach was based upon the notion that different risks are posed by the same chemicals in different waste forms. More specifically, the physical nature of stabilized wastes, their ability to reduce the mobility of chemicals in the environment and the requirement to manage such waste in a landfill could provide additional protection. For example, stabilizing the waste and managing it in a landfill would help reduce or eliminate certain releases, such as windblown dust. By taking this additional protection into account, we could develop specific exemption levels that would be less stringent than those developed for the national generic option or the landfill-only option, but equally protective. The focus on stabilized waste forms was partially derived from a screening study that has been placed in the docket (see *Waste Forms Technical Background Document,* U.S. EPA, September 1998).

As explained in the background document, we decided not to further develop a stabilized waste option because of complications in defining which stabilized forms are appropriate and technical difficulties in determining what are the appropriate reductions in mobility from these forms.

VII. What Wastes Would Be Eligible for an HWIR Exemption?

A listed hazardous waste would be eligible for this exemption once all the HWIR exemption levels are achieved. Even though the wastes might still contain chemicals for which they were originally listed, concentrations at HWIR exemption levels would pose very low risk to human health and the environment. However, wastes which exhibit any of the hazardous characteristics would continue to be regulated as hazardous wastes until the characteristic is removed, even if HWIR exemption levels are achieved.

As discussed in Section XVIII of this preamble, we might not develop HWIR exemption levels for all ''chemicals of concern'' (HWIR exemption chemicals). Those wastes that would reasonably be expected to contain HWIR exemption chemicals without exemption levels would not be eligible for the exemption *even if those chemicals are not detected in the waste.* Chemicals can pose risk below levels capable of being detected by analytical methods. If a chemical does not have a risk-based HWIR level to compare against, we cannot evaluate whether it poses a risk below detection. Therefore, we believe that any waste that would be reasonably expected to contain an HWIR exemption chemical that does not have an exemption level should be ineligible for the HWIR exemption, regardless of test results. See Section IX.A for further discussion of this issue.

VIII. What Level of Governmental Review Would Be Needed for an HWIR Exemption Claim?

For both the generic and the landfill-only alternatives, the HWIR exemption would be self-implementing. Self-implementing means that no prior governmental approval or review of documentation is required before wastes are exempted from RCRA hazardous waste regulation. The use of a self-implementing mechanism is consistent with most other hazardous waste exemptions and exclusions, such as exemptions from the mixture and derived-from rules found in 40 CFR 261.3(c)(2)(ii) and exclusions from the definition of hazardous waste found in 40 CFR 261.4(b).

Self-implementation has several advantages: (1) The exemption can take effect quickly, (2) the generator's burden in claiming the exemption is reduced, and (3) the burden for the overseeing agency (the authorized State or an EPA Region) is also reduced. Most of the commenters to the 1995 HWIR proposal, including a majority of States, favored self-implementation.

Self-implementation would not prevent the overseeing agency from having a role in the HWIR exemption. As a condition of claiming an HWIR exemption, you would be required to provide specific information to the overseeing agency (see Section IX.D). In addition, you would be required to keep and retain records in order to maintain an exemption (see Section XI.C). This information would be available to the overseeing agency in an inspection and for an enforcement action, if needed. Because HWIR waste would be some of the lowest-risk industrial wastes, and the overseeing agency would still have authority to enforce against an improperly claimed exemption, we believe that there would be little benefit to requiring prior governmental approval before the exemption takes place.

In addition, your waste would only become exempt upon your receiving written confirmation that the notification package had been received by the overseeing agency. Examples of confirmation include certified mail return receipt, or written confirmation of delivery from a commercial delivery service. Upon receipt that the notification package has been delivered successfully, you would be allowed to manage the HWIR waste as nonhazardous. Confirmation that the overseeing agency has received the package would not imply, however, that the package has been reviewed or approved.

As noted above, since our preferred option is to make the HWIR exemption self-implementing, the overseeing agency would not be required to make a decision regarding the waste prior to exemption. We do not believe that requiring a waiting period (for example, 30 or 60 days) before the exemption becomes effective is necessary. Most of the commenters to the 1995 HWIR

proposal, including representatives of industry, federal and state government agencies, utility associations, industry associations and waste management associations opposed the idea of a waiting period. They felt that such a waiting period could create undue expense, administrative burden, and numerous legal and practical complications (such as storage space issues).

Some of the commenters on the 1995 HWIR proposal, including some State governments, favored having the option of requiring prior approval and a waiting period. One possible approach would to require a waiting period which could be used by the overseeing authority to review the notification package. This review would be discretionary. If the overseeing authority takes no action during this waiting period, then the exemption would be approved. Commenters on the 1995 HWIR proposal who favored a waiting period felt that it would allow the overseeing agency time to screen notifications and obtain additional information as necessary. Waiting period recommendations ranged from 30 days to 90 days.

We request comment on whether HWIR should be self-implementing, and whether there should be a waiting period before the exemption take effect.

IX. For the Generic HWIR Exemption, What Steps Would I Follow Before My Waste Could Be Exempted?

You would be required to complete the following steps before your waste could be exempted:

(a) Determine which HWIR exemption chemicals of concern your waste is reasonably expected to contain. (see Section IX.A below)

(b) Develop a waste sampling and analysis plan (see Section IX.B.1).

(c) Determine that the concentrations of the chemicals reasonably expected to be present in your waste are at or below the appropriate exemption levels (see Section IX.B.1).

(d) Determine that the waste does not exhibit any of the hazardous waste characteristics of Subpart C of 261.

(e) Notify the overseeing agency that you are claiming an exemption under this Subpart for your waste (see Section IX.D).

Once you receive confirmation that your notification was received by the overseeing agency, then your waste is exempt. Figure 1 provides an overview of this process, which is described in more detail in the sections that follow.

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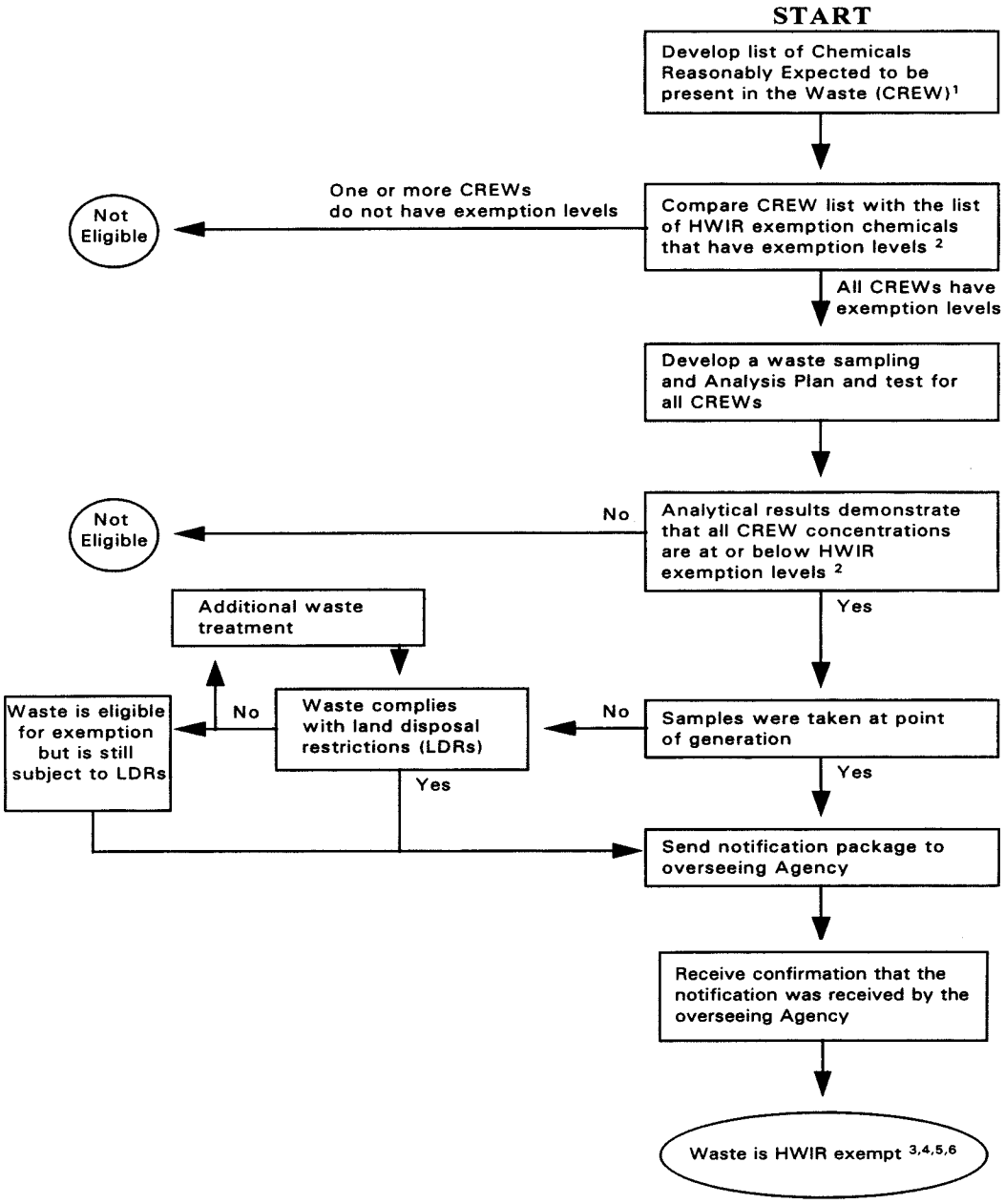
Figure 1. Obtaining an HWIR Exemption for a Listed Hazardous Waste



[1] CREWs include: (1) chemicals identified as the basis for the listing, (2) chemicals requiring LDR treatment for that waste, (3) chemicals detected in any previous analysis of the waste; (4) chemicals introduced into the process that generates the waste; and (5) chemicals that are known to result from side reactions or are byproducts of the process that generates the waste.

[2] There are two sets of exemption levels, one representing the "generic" exemption and the other representing the "landfill-only" exemption. Note that although you only have to analyze for CREW, all chemicals from Appendix X must be at or below the HWIR exemption levels.

[3] The waste is not exempt if it exhibits any of the hazardous waste characteristics.

[4] The HWIR exempt waste must be managed in accordance with the State non-hazardous waste program.

[5] Waste that exited Subtitle C under the "landfill-only" exemption are prohibited from placement on the land before disposal, must be disposed in a landfill, and must be tracked to ensure that the wastes are received by a landfill.

[6] Periodic sampling and analysis are required in order to maintain the HWIR exemption.

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A. For Which Chemicals Would I Have To Analyze To Obtain an HWIR Exemption?

To claim the HWIR exemption for your candidate waste (''HWIR waste''), you would have to determine for which chemicals listed in the new 40 CFR Part 261 Appendix X (found in Table 2, in Section XIV of this preamble) you would have to analyze. You would have to test your HWIR waste for all chemicals reasonably expected to be present, which includes the following:

1. Chemicals identified as the basis for listing the waste. (For F and K listed waste, these chemicals are found in Appendix VII of 40 CFR 261. For P and U listed waste, these are the chemicals named in the specific listings found in 40 CFR 261.33);

2. Chemicals listed in the table ''Treatment Standards for Hazardous Wastes'' contained in 40 CFR 268.40 as regulated hazardous chemicals for LDR treatment of the waste;

3. Chemicals detected in any previous analysis of the waste;

4. Chemicals introduced into the process that generates the waste; and

5. Chemicals that are known to result from side reactions or are byproducts of the process that generates the waste.

You would not be required to test for every chemical found in the new 40 CFR Part 261 Appendix X (which contains the broad set of chemicals ''of concern'' discussed in XVII.A of this preamble). You could use process knowledge to determine if a chemical other than those included in the five categories referenced above might be present in the waste. If you were to determine that the chemical is not reasonably expected to be present in the waste, you do not need to test for it. However, you would be responsible for ensuring that the waste meets all HWIR exemption levels. If at any time the waste fails to meet the levels, then the waste stream is not exempt. Additionally, you would be also responsible for determining whether your waste exhibits one of the hazardous waste characteristics set out in Subpart C of part 261.

We request comment on the above guidance for determining which chemicals are ''reasonably expected to be present.'' In particular, we request comment on whether and how to adjust this definition for some of the broader waste listings, such as electroplating operations (RCRA waste code F006) or spent solvents (RCRA waste codes F001–F005). These listings represent multiple processes, and any particular process would not necessarily contain all the chemicals for which the broad waste code was listed. For example, a chrome plating waste might not necessarily contain nickel, even though nickel is one of the chemicals associated with F006 wastes.

In addition, as discussed in Section XVII of this preamble, we might not develop exemption levels for all HWIR chemicals. If your waste would reasonably be expected to contain HWIR exemption chemicals that do not have levels, that waste would not be eligible for the exemption even if that chemical is not detected in your waste. The reason we believe that such wastes should be ineligible is that chemicals can pose risk below analytical method detection limits.

If a chemical does not have a risk-based HWIR level to compare against, we cannot evaluate whether a waste poses a risk below its analytical detection limit. Therefore, any waste that would be reasonably expected to contain an HWIR chemical that does not have an exemption level would not be exempted, regardless of test results. Unlike the 1995 HWIR proposal, under this approach you would only be required to test chemicals that are or have historically been associated with the waste (either through the original listing, the LDR requirements, or generator knowledge). Therefore, we believe it is reasonable that for those chemicals, an absence of a risk-based standard would prevent the associated waste from becoming exempt.

We did not encounter this issue in our 1995 HWIR proposal because we assigned every chemical an exemption level either through modeling or through an extrapolation methodology. We have subsequently discarded the extrapolation methodology because both the public comments and our own internal review indicated that it did not have a firm enough scientific basis. We request comment on this policy to exclude from HWIR eligibility those wastes are reasonably expected to contain chemicals that do not have HWIR exemption levels.

B. How Would I Have To Sample and Analyze My Waste Stream When Seeking an Exemption Under HWIR?

Under today's approach, you would have to sample and analyze for all chemicals that you determined are reasonably expected to be present in your waste stream. In addition to the initial testing described below, you would also be required to retest your waste stream after it is exempted to ensure ongoing compliance. It remains your responsibility to ensure that a waste stream always meets the exemption requirements for all HWIR exemption chemicals, regardless of which chemicals you would be required to test, how many samples you consider, or how often you retest.

The discussion that follows explores, in some depth, a number of issues related to the characterization of your waste stream and the determination of compliance with the HWIR exemption's testing requirements. For each waste stream that you seek to exempt, you would have to develop and follow a written plan for sampling and analyzing your waste stream. This plan is discussed in Section IX.B.1. You must analyze at least four samples and must document the results from all samples analyzed. Waste stream characterization and appropriate methods are discussed in the remaining parts of Section IX.B. For every chemical tested, each sample must show that the total concentration is at or below the exemption level. This standard of compliance is discussed in Section IX.B.2. Possible alternatives to this standard of compliance are discussed in Section IX.C. Together, these elements form the core testing requirements for a generator initially seeking exemption. Subsequent testing requirements and the frequency of such testing are discussed later in Section XI.A of this preamble.

1. *Waste sampling and analysis plan.* The waste sampling and analysis plan is a planning document used to define the necessary criteria and quality control requirements for sampling, analysis, and data assessment. We recommend that these plans be developed consistent with the guidance provided in the applicable sections of ''Test Methods for Evaluating Solid Waste, Physical/Chemical Methods'' (SW–846). More specifically, chapters within this document that should be helpful to you include Chapter One that describes basic quality assurance and quality control procedures, Chapter Nine which provides guidance on sampling strategy, and sampling techniques, and Chapter Two that identifies appropriate methods for samples based upon sample matrix and the analytes to be analyzed.

You would be required to develop a waste sampling and analysis plan prior to testing your hazardous waste stream for compliance with the HWIR exemption levels. Your waste sampling and analysis plan would be required to contain the following information:

a. The chemicals for which each waste stream will be analyzed and the rationale for the selection of those chemicals;

b. Sampling strategy, and methods used to obtain representative samples of the waste stream to be analyzed;

c. The sample preparation, clean-up, if necessary, and test determinative

methods used to analyze for these chemicals; and

d. Sufficient sampling procedures and locations to characterize the entire waste stream.

You might already have a waste sampling and analysis plan in place because of general facility standards for treatment, storage or disposal facilities (see 40 CFR 264.13 and 265.13), or because of land disposal requirements (see 40 CFR 268.7(a)). The key elements of an HWIR waste sampling and analysis plan are consistent with these other waste analysis plans (See *Waste Analysis at Facilities that Generate, Treat, Store and Dispose of Hazardous Waste*, U.S. EPA April 1994). You can create a separate waste sampling and analysis plan for your HWIR exemption or you could modify existing plans to fulfill both HWIR and LDR requirements. Be aware that a modification to your existing waste sampling and analysis plan could require a permit modification.

2. *Waste stream characterization and demonstration of compliance with the HWIR exemption levels.* You would have to obtain representative samples and analyze your waste stream to ensure that it is properly characterized. Such samples should be collected in an unbiased manner, that is, one which gives all samples an equal chance of appearing to represent the population. Analysis of such samples should statistically represent concentrations in the waste stream in terms of averages and variation. Finally, such samples should preserve the waste's composition and to prevent contamination or changes in concentration of the parameters to be analyzed.

You would also have to evaluate your waste stream using the maximum detected concentrations based upon the complete extraction of HWIR exemption chemicals. If any sample contains a chemical at a concentration greater than its specified exemption level, then the waste stream would be ineligible for the HWIR exemption.

The specific exemption levels your waste must meet depend on the regulatory option under which you seek to exempt your waste (generic and landfill-only options). The two regulatory options, which are discussed in Section VI, would have separate exemption levels. In addition, the different waste form categories within the generic option (liquid, semi-solid, solid) would have separate exemption levels. (See Section XIX.C for a discussion of this waste form categories). The format of the exemption levels table is presented in Table 3 found in Section XIV of this preamble. Meeting the appropriate exemption level requires that the concentration of each sample be at or below that exemption level.

Because any sample above the HWIR exemption levels would disqualify the waste stream from the exemption, this could provide an incentive to take as few samples as possible. To have adequate confidence that the waste stream is properly exempt, today's approach would require a minimum number of samples. In constructing this requirement, we do not want to overprescribe sampling in cases in which you seek to exempt a homogeneous waste stream whose true average concentrations are substantially below the exemption level.

We believe that a minimum of four samples at each testing event is reasonable. This minimum number of samples conforms to the requirements developed for the delisting program and established in its guidance (see *Petitions to Delist Hazardous Wastes: A Guidance Manual*, U.S. EPA March 1993). In addition, at least four samples are often used to characterize your waste stream using common statistical measures of average concentration (sample mean) and variability (standard deviation), and can be used to determine if additional samples are appropriate.

This minimum number of samples should not be assumed to be the same as an appropriate number of samples. The appropriate number of samples should be consistent with the characterization of the waste stream and the distribution of concentrations recorded as a result of the samples taken. As specific requirements for the HWIR exemption, you would have to take at least four samples and to characterize your waste stream.

The number of samples you would have to take would have to be sufficient to represent variability throughout the waste stream and across time. We recognize that solid wastes are often not homogeneous and are by nature generally heterogeneous. Solids are also frequently difficult to completely mix. Thus, more than four samples might be needed. You should use your knowledge of the process generating the waste stream to help determine the appropriate number of samples. The greater the variability within the waste, the more difficult it is to determine whether your samples are representative of the entire waste stream. One way to improve sampling precision is to increase the number of samples. In addition, you can improve your information on the variability of chemical concentrations within the waste stream by analyzing grab samples.

Because generators of many different kinds of waste streams might seek exemption under HWIR, we have no preconceived notions on how variable your particular waste stream might be. Sampling of a heterogeneous waste with highly variable concentrations would require a greater number of samples, as contrasted with relatively homogeneous wastes with mean concentrations well below the exemption levels. In addition, the longer the time period over which you might need to establish the variability of the waste stream, the greater the number of samples you should take. For waste streams that experience wide variability in chemical concentrations over time, you should discuss, in your waste sampling and analysis plan, how your sampling strategy addresses such variability.

You still would continue to be responsible for ensuring that your waste streams always meet the appropriate exemption levels. We discuss, in a background document, estimates regarding numbers of samples. This document explores sample sizes for different waste streams, for the not-to-exceed compliance standard (the preferred approach) as well as alternative compliance standards discussed later under subsection C of this part of the preamble (see *Estimates of Sample Sizes Required for a Generator to Demonstrate a Waste Qualifies for Exemption Under HWIR*, U.S. EPA, May 1999).

We request comment on both the need for a minimum number of samples and what that minimum number should be.

Allowing no samples to exceed the HWIR exemption level provides a clear standard against which both you and the overseeing authority can refer for compliance and enforcement purposes. Such clarity is especially important in the context of a self-implementing regulatory mechanism, because the overseeing agency would not scrutinize the waste sampling and analysis plan in advance to determine if such methodologies were chosen and applied correctly.

As noted in the 1995 HWIR proposal, enforcement authorities prefer the practicality of a strict maximum standard. Inspectors seek to independently collect samples for analysis over a short time span. An exceedance by any sample during an inspection could constitute a violation.

In some cases, you might also be required to demonstrate compliance with LDR sampling and analysis requirements. For example, wastes that become exempt after the point they are generated would have to still fulfill LDR requirements. To demonstrate

compliance for the LDR program, ''all portions of the waste must meet the applicable treatment standards, that is, no portion may exceed the regulatory limit.'' (63 FR 28556, 28567 (May 26, 1998)). Thus requiring that all samples be at or below the exemption levels would be consistent with the approach used in the LDR program.

We recognize limitations to the strict maximum standard. As noted by commenters to the 1995 proposal, you would have to effectively meet a much lower average concentration level to maintain confidence that no sample would exceed the HWIR exemption level. However, as the purpose of HWIR is to exempt only waste streams that are clearly nonhazardous, imposing a strict maximum makes continued compliance more certain for wastes with chemical concentrations far below the exemption levels. Wastes with chemical concentrations near the exemption level, especially wastes with some significant degree of variability, may not be the most appropriate candidates for a self-implementing HWIR exemption.

However, unlike the development of the LDR regulatory standards and its implementation of a strict maximum, the HWIR model as designed would not incorporate variability into the exemption levels. Within the LDR standards, we set a maximum acceptable chemical level for a particular waste treatability group, based on the performance of the Best Demonstrated Available Technologies (BDAT). This maximum incorporates fluctuations in performance for well-designed and well-operated treatment systems and thereby ''builds in'' variability into the standard itself. This maximum is calculated as the mean of individual performance values multiplied by variability and recovery factors.

In developing LDR concentration based treatment standards, we did not believe that incorporating variability relaxed the requirements of Section 3004(m), but rather represented a response to ''normal variations in treatment processes. As a practical matter, facilities will have to incorporate variability factors into process design to ensure performance that is more stringent than the standard to ensure continuous compliance with the standard.'' (see BDAT Background Document for QA/QC Procedures and Methodology dated October 23, 1991). In contrast, for the purposes of the HWIR exemption levels, there were no data or estimates of concentration variability within wastes. Therefore, adjustments to the HWIR exemption levels would not have the same informational basis available for incorporating variability into the regulatory standard.

We request comment on the strict maximum standard against which to evaluate a waste stream for an HWIR exemption. Alternatives to the strict maximum are discussed in Section IX.C below.

3. Selection of a reliable analytical method to test your waste stream. We would not specify which method you would use to evaluate chemical concentrations in waste; you may select any reliable analytical method. However, you would have to establish and document that the performance of the selected method demonstrates that the HWIR exemption level was achieved.

You would also have to demonstrate that the analysis could have detected the presence of a chemical at or below the specified exemption level. We would consider that the HWIR exemption level was achieved if you indicate that the chemical concentration of a spiked sample is at or below some fraction of the exemption level within analytical method performance limits (for example, sensitivity, bias and precision). To determine the performance limits for a method, we recommend following the quality control (QC) guidance provided in Chapters One and Two of SW–846, and the additional QC guidance provided in the individual methods. As discussed in the 1995 HWIR proposal, detection at, but not below, the exemption level may not be sufficient to establish a reliable method, because such detection would not demonstrate the absence of the chemical with sufficient confidence (60 FR 66377). At a method's limit of quantitation, results may be obtained with a specific degree of confidence, generally with an uncertainty of plus or minus 30% in the measured value (see Keith, L.H., *Environmental Sampling: A Practical Guide*, 1992). The relative uncertainty would be expected to be much lower as the concentrations increase above a method's quantitation limit. Again, quality control guidance found within SW–846 and associated with the individual methods should assist in identifying the necessary performance.

Your method would also have to attain acceptable recovery for the chemicals under analysis. Such recovery is dependent upon the waste matrix being analyzed and has ranged from 80–120% for method development activities, volatile organics (using relative recoveries), and for inorganics in almost all matrices. Analyses of certain other chemicals (extractable organics) can achieve slightly smaller recoveries (70%+), and for a few ''difficult'' matrices, we have considered sample preparation appropriate if it generates recovery of 50% or greater. These issues are discussed within a recent Agency memorandum (see *Appropriate Selection and Performance of Analytical Methods for Waste Matrices Considered to be 'Difficult to Analyze'*, U.S. EPA memorandum, January, 1996). In the development of LDRs, methods with less than 20 percent recovery have been discarded from the calculation of treatment standards (see *BDAT Background Document for QA/QC Procedures and Methodology*, U.S. EPA, October 23, 1991).

If you have trouble meeting these acceptable levels of recovery, you may be using an inappropriate method, may not have pursued appropriate alternative methods (consistent with guidance on method modification), or may be faced with the lack of an existing, validated method. In the case in which an existing method or appropriate alternative will not achieve acceptable recoveries, we request comment on correcting such analyses for the bias introduced by these deficiencies in recovery. Bias introduced by partial recoveries refers to the systematic deviation of analytical results due to matrix effects. It can be assessed by comparing measurements to an accepted reference value in a sample of known concentration or by determining the recovery of a known amount of contaminant spiked into a sample (that is, a matrix spike). Given the potential for using different methods, adjustments with respect to recovery can make the results from different methods more comparable.

We specifically request comment on the option of requiring that analytical protocols achieve a minimum of 20% recovery, and that analytical results with analytical spike recovery of less than 100% be corrected for the percent recovery determined for that waste before being compared to the HWIR exemption level. This adjustment would allow the greatest flexibility in the choice of analytical procedures, provide equivalency between different procedures, and allow those matrices that are difficult to analyze to be considered for exemption.

Finally, we seek to address potential technical limitations of analytical methods in quantitating to concentrations identified through the HWIR risk modeling. In the 1995 HWIR proposal, we suggested the use of detection limits to serve as exemption levels in cases where the exemption

levels fell below proposed ''exemption quantitation criteria'' or EQCs. Such EQCs were defined as the lowest levels that can be reliably measured within acceptable limits of precision and accuracy during routine laboratory operating conditions using appropriate methods (60 FR 66377). For chemicals that had modeled or extrapolated levels below their EQCs, we set the exemption level for these chemicals at the EQC and required the application of LDR treatment standards, regardless of whether the waste was to be land disposed. We also discussed the alternative of making wastes containing chemicals with analytical limitations ineligible for an exemption, but expressed concerns about the impact such a policy would have on eligible waste volumes.

We continue to harbor concerns about the impact that technical limitations might have on waste eligibility, but are equally interested in creating continuing incentives for generators to improve their analytical methods and quantitate to levels selected on the basis of risk. We have historically noted and continue to recognize increased sensitivity of analytical methods over time. Levels of quantitation are also driven by market demands, and by setting exemption levels on the outer reaches of current methods, we seek to have the market modify and develop methods to reach these levels. Commenters to the 1995 rule encouraged the continued pursuit of analytical methods, possibly through revisiting such EQC determinations over time.

We are also interested in bolstering the relationship of the exemption levels to the underlying risk assessment and therefore, seek to avoid the adoption of levels not related to risk; established quantitation levels (for example, EQCs) and LDR treatment standards are not based on risk assessment and therefore are not ideal for identifying HWIR waste as non-hazardous. Therefore, in seeking exemption under HWIR, you would have to use and modify, as necessary, reliable analytical methods to determine if concentrations in your waste meet the exemption levels.

In 1995, we received comments both supporting our application of EQCs as exemption levels and rejecting such usage as not associated with risk. Under another alternative, we could use the detection limit in place of the risk-based level, if the risk associated with the detection level concentration is judged to be within an acceptable range of risk (even if not meeting the primary risk objectives). We request comment on the option of using the detection limit in place of the HWIR exemption level when the detection limit is higher, but still within an acceptable level of risk.

C. What Alternatives Has EPA Considered for Demonstrating Compliance With the Exemption Levels?

1. *EPA requests comment on alternative standards for compliance.* As explained previously, we would require all samples to have concentrations at or below the HWIR exemption level. However, we did consider alternative standards for compliance. These alternative standards would allow the mean chemical concentration within the HWIR waste to be closer, yet still at or below the HWIR exemption level. Such alternatives would allow greater variability in sample concentrations near the exemption level and, to a modest extent, allow chemical concentrations from individual samples to exceed the HWIR exemption level, while maintaining the mean to be below the exemption level.

We believe that it might be appropriate to consider alternatives that would allow chemical concentrations from individual samples to exceed the HWIR exemption level because of the nature of the risk assessment used to set those levels. The HWIR risk assessment considers only chronic risk. Therefore, the levels are based on average exposure to a chemical over a lifetime, not on one-time events. In addition, the current version of the risk modeling does not consider variations in waste concentrations within a calendar year.

Specifically, we request comment on three alternative regulatory standards: (1) The upper confidence limit associated with the estimated mean concentration in the waste would have to be at or below the HWIR exemption level at some level of confidence; (2) the estimated mean chemical concentration within the candidate waste would have to be at or below the HWIR exemption levels, and the concentration of individual samples would be required to be at or below some multiple of the exemption level; and (3) the estimated mean concentration would have to be at or below the HWIR exemption level, and the upper confidence limit associated with the estimated mean (at some level of confidence) would have to be at or below some multiple of the exemption level.

Within the upper confidence level approach under alternative (1), you would have to demonstrate that the upper confidence limit around the estimated mean concentration in the waste is below the HWIR exemption level at some specified level of confidence. This approach was used in the comparable fuels rule which required the upper confidence limit at 95% confidence to be below the exclusion level (see 63 FR 33782).

An upper confidence limit approach has advantages in that it allows for a degree of variation in the concentration of individual samples in the waste. The mean would be required to be below the HWIR exemption levels; however, occasional values above the exemption level would be tolerated. The approach is self-implementing in the determination of the number of samples required and it is consistent with the way RCRA wastes are often assessed for the toxicity characteristic.

An upper confidence limit approach also provides continuing incentives to better characterize the wastes. Within the strict maximum approach, the more samples you take, the greater the likelihood that one sample would fail. With an upper confidence limit approach, the more samples that you take, the better that you can establish the upper confidence limit associated with the mean (that is, the more precise your estimate is of the mean). With an upper confidence limit approach, wastes with mean concentrations near but below the exemption level could be exempted by taking enough samples to bring the upper confidence limit below the exemption level. You would need to determine whether the value of the exemption justifies the cost of sampling.

Specifically requiring a minimum number of samples is unnecessary with an upper confidence limit approach. The number of samples is directly calculable from the confidence level chosen, the standard deviation of the distribution, and the distance between the mean and the exemption levels.

An upper confidence limit would provide the maximum flexibility in selecting the sampling, analytical and statistical methods for establishing an HWIR exemption. Although an upper confidence limit is a statistically based performance criterion, that does not mean you would have to perform a large number of chemical analyses nor employ complex statistics.

However, we are concerned about prescribing statistical methods for evaluation of HWIR compliance. Inspectors would still have the right to enforce based on grab samples, and inspectors would find it difficult and resource intensive to replicate the type of sampling needed to construct a statistically based upper confidence limit. Therefore, disagreements between you as the generator and inspectors could engender involved statistical comparisons as well as increased costs in resolving compliance status.

The second alternative requires both the average chemical concentration to be below the HWIR exemption levels, and the concentration of individual samples to be below some multiple of the exemption level. Requiring all individual samples to be below a multiple of the exemption level restricts the potential variability of the waste. Only wastes with modest variation (and/or the ability to maintain lower average levels) are likely to meet HWIR exemption levels.

Consistent with the no exceedance approach, a minimum number of samples would need to be required under this alternative. There would be a similar incentive not to test your waste, because the more samples you take, the greater the probability of finding an individual sample that would fail.

This alternative could be of benefit to both you and enforcement officials. Enforcement officials would have one concentration level against which to evaluate compliance, and you would have a standard that would tolerate some variation in the waste around the exemption level and permit individual samples to exceed the exemption level.

Making assumptions about the underlying distribution and ranges of waste stream concentrations and adopting the same approach that we used to develop variability factors under the LDR program, we suggest a multiple for this evaluative standard of 2.8. Note that we do not adjust the regulatory standard below which the average concentration in the waste stream would have to reside, but rather are suggesting a ceiling for any individual sample be based upon a similar kind of adjustment as the one used in the LDR program. Whereas the LDR adjustment was based on data from specific treatment processes, the multiple applied to the exemption level to derive this ceiling is established based on assumed characteristics of the underlying distribution of concentration in waste. Actual concentrations across a wide range of real waste streams will vary much more considerably. The specific derivation of this multiple can be found in the background document entitled ''Estimates of Samples Sizes Required for a Generator to Demonstrate a Waste Qualifies for Exemption Under HWIR.'' We request comment on the multiple of 2.8 and invite the suggestion of alternatives.

The third alternative combines elements of the first two alternatives discussed. The generator would calculate an upper confidence limit similar to alternative (1), but that limit would be required to be at or below some multiple of the exemption level rather than the exemption level itself. We would need to derive a basis for this multiple, consistent with the discussion of alternative (2).

This third approach would permit greater variability in the waste stream as compared to either the lead option in which no samples may exceed the exemption level and as compared to alternative (1) in which only a few samples falling outside the confidence interval could exceed the exemption level. Similar to alternative (1), we express concerns about prescribing statistical methods for evaluating HWIR compliance—disagreements can ensue in situations where the generator has established a confidence limit below the multiple of the exemption level, and, at the same time, the inspector finds an individual sample above this multiple of the exemption level.

Finally, and as implied by the use of confidence intervals within alternatives (1) and (3), either the generator or EPA would have to establish with what confidence theses statistical measures are evaluated. We believe that we should select the appropriate level of confidence. We recognize, however, that the use of confidence limits could rely on a fixed level of confidence for all waste streams or we could vary the specified level of confidence and require larger waste volumes to have greater confidence in the estimation of the mean than smaller streams. For example, we could require large, medium and small waste streams to achieve 98 percent, 95 percent, and 90 percent confidence, respectively.

We request comment on all three alternative approaches and specifically on the use of statistical measures and their consequences for enforcement, on the basis for establishing limits (for example, multipliers to the exemption levels) to which individual samples or confidence limits would have to comply, and on the selection of confidence limits and the appropriateness of varying such limits based on waste volume.

2. EPA requests comment on the use of grab or composite sampling, where appropriate, to demonstrate compliance. We are also considering whether to allow composite sampling as well as grab sampling for demonstrating compliance; our lead option presumes the use of grab samples. Composite sampling is a strategy in which multiple individual or ''grab'' samples (from different locations or times) are physically combined and mixed into a single sample so that a physical (rather than mathematical) averaging takes place. Composite samples provide average concentrations of a waste stream and, in contrast with grab samples, might reduce the number of samples needed to gain an accurate representation of a waste. Composite samples, though, are difficult for volatile organic compounds (VOCs) where analyte could be lost in the process of compositing.

To the extent that composite sampling achieves the goal of representing average concentrations in the waste, then the evaluation of composite samples for the purposes of HWIR compliance could be appropriate. This position was discussed in the 1995 HWIR proposal (60 FR 66386). In addition, the delisting program guidance suggests the use of composite samples. Both grab and composite sampling are used for the purposes of determining LDR compliance. Grab samples are required for all non-wastewaters and several wastewater streams, while composite samples taken over any one day are used for remaining wastewaters (see 40 CFR 268.40(b)).

Grab sampling is the preference of EPA and State enforcement officials. Grab sampling provides information about a waste's variability and the bounds of a chemical's concentration within a heterogeneous waste, while composite sampling yields information about average concentration. The resources necessary for enforcement to take composites over extended time periods is considered prohibitive. Furthermore, the use of composite samples for the purposes of HWIR compliance could create confusion if an enforcement official finds a grab sample that exceeds the HWIR exemption criteria while you found all composite samples to meet the HWIR levels.

Related to the concept of compositing is the size of each sample you may select for analysis. Currently, there is no specific guidance on the size of each sample to determine compliance with HWIR, and the selection of a very large grab sample would have a similar effect of physically averaging the concentration of a chemical within that sample. Greater physical sample size could also improve precision.

We request comment on the consideration of composite samples, particularly spatial composites, in evaluating a waste stream for HWIR compliance. We also request comment on the need to specify the size of samples taken to evaluate your waste stream.

D. What Information Would I Have To Include In the Notification Package to the Overseeing Authority?

Before managing any waste as exempt under HWIR, you would first have to send a notice to the Director of the State or EPA Regional authority that has jurisdiction over the facility generating the waste. We envision this notice as a tool for the overseeing agency to document and track exemptions, not as a means to review and verify exemption claims.

The overseeing agency would be under no obligation to undertake a review of exemption claims prior to the exemption becoming effective. However, failure to undertake such prior review would not preclude a subsequent enforcement action, should the exemption claim later be determined to be inaccurate or otherwise invalid.

For this reason, we prefer to keep information requirements in the notification package to a minimum and to require that specific information documenting individual exemption claims (such as the sampling and analysis information) be kept on-site at the generating facility.

The notification package would have to be sent by certified mail or other mail service that provides written confirmation of delivery. You would be required to include the following in the notification package:

(a) The name, address, and RCRA ID number of the facility claiming the exemption;

(b) The applicable EPA Hazardous Waste Code of the exempted waste and the narrative description associated with the listing from Part 261, subpart D;

(c) A brief, general description of the process that produces the waste;

(d) An estimate of the average monthly, maximum monthly, and annual quantities of the exempted waste (we are suggesting a simple check box system);

(e) A statement that you are claiming the HWIR exemption for the waste;

(f) A certification—signed by you or your authorized representative—that the information in your notice is true, accurate and complete.

To give you an idea of what this notification package would look like, we have included a sample form in the docket (see *Sample Notification Form for Waste Claiming Exemption Under the Hazardous Waste Identification Rule (HWIR),* U.S., EPA July 1999). We request comment on this form of notification and alternatives such as electronic submission.

We also request comment on whether to require additional information in the notification package, such as the list of chemicals found in the waste and a summary of results for each sample analyzed. The implementing agency could find such summary information helpful in planning and prioritizing inspections.

E. What Is the Role of the Public in the HWIR Exemption Process?

In recognition that issues surrounding hazardous waste management often arouse public sentiments, EPA developed a framework for public participation under RCRA. This public participation framework seeks to both formalize responsibilities of facility owners and operators under RCRA, and to enhance citizen opportunity for involvement in local environmental decision making. Regulations, such as the permit modifications procedures in 40 CFR 270.42 (52 FR 35838) and the changes to 40 CFR Part 124 (procedures for processing permit applications) codified in the ''RCRA Expanded Public Participation'' rule (60 FR 63417–34, December 11, 1995), have made facility owners and operators responsible for a number of public participation activities (such as public notices, public meetings, and information repositories).

In addition to the statutory and regulatory requirements cited above, EPA has published the ''RCRA Public Participation Manual'' (EPA530–R–96–007). This manual outlines public participation procedures and guidance to staff in EPA and RCRA-authorized state programs, to assist them with ensuring that the public has an early and meaningful role in the RCRA permitting process. This manual also provides public participation guidance to regulated industries and the communities that interact with them.

Finally, EPA has also established several mechanisms in addition to the RCRA Information Center (the Docket) for promoting public access to information regarding RCRA, including a citizens' RCRA hotline, an Internet Web site, and a searchable database of all RCRA related policy documents (''RCRA Online'').

In the 1995 HWIR proposal, we proposed requiring the HWIR waste generator to notify the public of exemption claims, through publication of newspaper notices local to facilities that generate and/or dispose of HWIR waste. However, other types of hazardous waste determinations do not require such notices. Because the HWIR exemptions levels would be based upon a nationally protective risk analysis, we do not believe that site-specific public notices of exemption claims are necessary. We believe that the existing mechanisms discussed above provide opportunity for interested parties to become informed and involved and to influence RCRA program development and implementation.

We also understand that on the State level, many environmental agencies have mechanisms in place, such as telephone hotlines, print or electronic media, to answer questions about public safety and environmental issues. State environmental agencies would have the option of making information contained in notification packages from each generating facility in the respective State available to the public. Depending upon the structure of State programs, the State agencies could decide to keep the information available at State offices, or to delegate the information-sharing role down to the local level at public libraries, schools, or fire stations. As discussed in the previous section, today's notice, unlike the 1995 HWIR proposal, does not advocate requiring the submission of testing information as part of the notification package. Under this approach, however, the information that the States could share with the public would not contain the testing results.

Another possible approach to this issue is to keep the exemption self-implementing except when there are adverse public comments on the exemption. Under this approach, you, as the person claiming the exemption, would publish a notice in a local paper explaining the exemption. If you receive no adverse comments, then you would send a certification to this effect to the overseeing agency with the notification package. When you receive the written confirmation that the notification package has been received, then the waste would be exempt.

On the other hand, if you do receive adverse comments, then you would forward those to the overseeing agency with the notification package. The waste would not be exempt until the overseeing agency approved the package. This approach would have the advantage of targeting the overseeing agency's resources toward reviewing those exemptions that are of most public concern, and also giving the person claiming the exemption assurance that the overseeing agency supports the claim.

We are taking comment on these issues of public notification and access to information related to HWIR exemption claims. Specifically, we request comment on (1) whether existing mechanisms for information sharing, including access via the Internet, are sufficient to provide the public with information relative to

individual HWIR exemption claims asserted in each State, (2) whether it is instead appropriate to notify the public of HWIR exemption claims through such mechanisms as newspaper notices at either the waste generating or the disposal facility prior to having the exemption claims become effective, and (3) whether the receipt of adverse public comments should trigger review of the package by the overseeing agency. We also request comment on whether to include testing results information in the notification package for the purpose of greater public access to this information.

X. Once the Waste Becomes Exempt, What RCRA Requirements Might Still Apply?

A. Where Could HWIR Waste Be Treated or Disposed?

Under the generic HWIR exemption, there would be no conditions imposed on the management of the exempted waste. The waste would no longer be subject to regulation as a hazardous waste under Subtitle C, and therefore would be treated and disposed in accordance with State regulations governing the management of other nonhazardous industrial waste.

Under the contingent management HWIR exemption, HWIR waste would have to be disposed of in a landfill. This landfill does not need to be a hazardous waste landfill, but it would be regulated under existing State requirements for nonhazardous waste landfills, which would help ensure that it is protective of human health and the environment.

Under both options, the waste might also have to meet LDR requirements (see Section X.C).

B. Would a Manifest Be Needed To Track Where the HWIR Waste Was Shipped Off-Site?

For exemptions using the generic option, we do not believe that tracking is necessary, since the levels for the exemption are based on modeling destinations for appropriately managed nonhazardous industrial waste. This judgement is consistent with existing State nonhazardous waste programs, which do not require a specific tracking mechanism as nonhazardous waste travels from the generator to its point of disposal. We request comment on whether under the HWIR generic exemption we should require that paperwork accompany the waste in order to track the waste and provide notice to the receiving facility that the waste is HWIR-exempt.

For exemptions using the landfill-only option, we believe that tracking of some sort might be needed to ensure that the waste is, in fact, disposed in a landfill. The landfill-only HWIR exemption levels are based on disposal in a landfill; other destinations might not meet our risk protection criteria. We evaluated a number of options for tracking landfill-only HWIR exempt wastes, including requiring the use of a uniform hazardous waste manifest, which is required for hazardous waste generators shipping waste off-site. However, instead of requiring uniform hazardous waste manifest tracking, we suggest an alternative tracking requirement for the landfill-only exemption (See Section XII.B for further discussion of the alternatives.)

C. How Would Land Disposal Restriction (LDR) Requirements Apply to the HWIR Waste?

Wastes that have been shown to have met the HWIR exemption levels at the point of generation would be considered by EPA to have never been hazardous and, therefore, would have no LDR obligation. Wastes that have met the HWIR exemption levels *after* the point of generation, however, would still be subject to LDRs even after they become exempt from the definition of hazardous waste, because LDRs apply to wastes that are hazardous or have ever been hazardous.

HWIR wastes that are subject to LDRs are also subject to the ban against using dilution to achieve LDRs (40 CFR 268.3). However, HWIR wastes that are not subject to LDRs would not be subject to this ban. For example, wastewaters managed solely in tanks and discharged under the Clean Water Act (CWA) are not managed on the land and therefore not subject to the LDR dilution ban.

We considered whether to specifically prohibit the use of dilution to achieve the HWIR exemption levels. Our intention in developing HWIR is to exempt wastes that are low risk due to pollution prevention or treatment, not to encourage dilution. Dilution would be inconsistent with the Congressional purpose of encouraging waste minimization. The legislative history of RCRA indicates that a prohibition on dilution ''is particularly important where regulations are based on concentrations of hazardous constituents'' (H.R. Rep. no. 198, Part I, 98th Congress, 1st Session 38 (1983)).

Since HWIR wastes that would be subject to LDRs would also be subject to the ban against using dilution to achieve LDRs, adding a specific dilution ban for HWIR could be redundant for all wastes subject to the land disposal restrictions. However, HWIR wastes that are not subject to LDRs would not be subject to this ban, and are identified as (1) wastes with chemical concentrations below LDR levels but above HWIR levels, and (2) wastes that are not managed or disposed on the land.

For example, wastewaters managed solely in tanks and discharged under the Clean Water Act (CWA) are not managed on the land and therefore not subject to the LDR dilution ban. For such wastewaters managed in tanks, it might be difficult in some cases to determine if intentional dilution is occurring. Combining wastewaters for treatment purposes before discharge under the Clean Water Act is often the most efficient and effective way of treating them.

Generally, we oppose the dilution of waste consistent with stated waste minimization policies to reduce the volume and toxicity of wastes (see Section 1003 of RCRA), but we also recognize that the aggregation of wastes amenable to the same type of treatment is legitimate and desirable, even though chemical concentrations within such wastes might decrease. In promulgating regulations under the LDR program, we provided guidance regarding such aggregation as permissible dilution, despite the overall dilution ban. Aggregation is considered legitimate if all wastes are amenable to the same type of treatment and this method of treatment is utilized for the aggregated wastes (55 FR 22666). Several commenters to the 1995 HWIR proposal, while supportive of an HWIR dilution ban, felt that aggregation for purposes of transfer and treatment in wastewater systems should not be considered impermissible dilution. By adopting similar guidance for HWIR, we could prevent inappropriate dilution, but allow for appropriate aggregation for the purposes of treatment.

We request comment on whether to specifically prohibit dilution as a means of attaining the HWIR exemption levels. We also request comment on the appropriateness of considering as permissible dilution aggregated waste streams directed towards centralized treatment for the purpose of meeting HWIR exemption levels.

XI. For the Generic HWIR Exemption, What Conditions and Requirements Would I Be Required to Fulfill To Maintain the Exemption?

A. Would I Have To Retest the Exempted Waste Stream?

Yes. Unless you only generate one batch of waste, you would have to periodically test the exempted waste stream as a condition of the exemption.

Failure to test and maintain documentation of this testing in accordance with the requirements under 40 CFR 261.57 would revoke the exemption. Post-exemption testing is needed to check for the continued compliance of the waste stream with the HWIR exemption levels and to maintain accurate characterizations of the waste stream. Note that a batch of waste would represent the amount generated prior to the next scheduled testing event (see Section XI.A.2 for discussion of testing frequency).

We would require the same sampling and analysis approach for subsequent testing as that required for the initial exemption (see Section IX.B of this preamble), and we request comment on the advantages and disadvantages of requiring the same testing scheme for both initial and subsequent sampling and analysis.

We also considered methodologies in which the data derived during the course of initial testing could be used as the basis for subsequent testing. A prediction limit derived from initial testing data could be used to evaluate continued compliance with the HWIR exemption. Prediction limits are designed to set an upper bound on the range of individual measurements that you would be likely to observe and still remain in compliance. If, during subsequent testing, any of the individual samples exceeded the prediction limit, there would be statistically significant evidence that the average concentration of the waste stream had changed and now exceeded the exemption level.

Although the prediction limit requires some statistical analysis, such prediction intervals are no more complicated to calculate than upper confidence intervals and are used in other parts of the RCRA program (see RCRA groundwater monitoring program 40 CFR 264.97). The use of prediction limits could also necessitate the collection of fewer samples over time to achieve the same amount of confidence that the waste stream remains appropriately exempt. However, because these prediction limits would be specific to a particular waste stream, compliance determinations would be more difficult and involved for the enforcing Agency.

We request comment on the potential use of prediction limits and other such techniques for the purposes of subsequent testing.

1. *For which chemicals would I have to retest the waste stream?* You would have to retest for all chemicals meeting the criteria for mandatory testing, unless the results of your testing demonstrated that, over the course of a year, the chemical was below the HWIR exemption level by an order of magnitude or more. In other words, if all samples taken during a twelve month period showed that a chemical was below one tenth of the HWIR exemption level, then no further testing for that chemical would be required. You continue to be responsible for the presence of these chemicals in your waste. Also, consistent with the previous discussion on reliable analytical methods, you would have to demonstrate that the analysis could have detected the presence of each chemical at or below one-tenth of the specified exemption levels.

The exception to this approach, as explained in Section XI.A.3 of this preamble, occurs when you have a change in the process generating your waste that introduces a new chemical or changes the concentration of existing chemicals. Then you would be required to test for all chemicals which are likely to be present, as explained in Section IX.A.

We request comment on the appropriateness of removing testing requirements for chemicals consistently detected less than one-tenth of the exemption level and whether this reduced testing obligation should occur after fewer or more testing events than those undertaken in one year. As currently structured, removing the obligation to test for certain chemicals after one testing event could mean as few as four samples having concentrations below an order of magnitude of the exemption level. Finally, we request comment on whether no further testing is appropriate for waste streams in which all chemicals are found to be below one-tenth of their exemption levels.

2. *How often would I have to retest the waste stream?* Retesting frequency would depend on the annual volume of the waste and whether it is a liquid or a non-liquid. Each year, you should document your annual generation of waste becoming exempt under HWIR for the purpose of establishing your retesting frequency.

If your waste is a liquid and it is generated in quantities	Then you would have to test your waste stream
Less than 35,000 tons/year.	Every 12 Months.
Between 35,000 and 500,000 tons/year.	Every 6 Months.
Over 500,000 tons/year.	Every 3 Months.

If your waste is a non-liquid (that is, a solid or semi-solid) and it is generated in quantities	Then you would have to test your waste stream
Less than 2,000 tons/year.	Every 12 Months.
Between 2,000 and 10,000 tons/year.	Every 6 Months.
Over 10,000 tons/year.	Every 3 Months.

We believe it is appropriate to vary the testing frequency based on both form and volume, because liquids are generally more homogeneous and therefore easier to characterize than solids. In addition, liquids are generated in significantly greater quantities. To require the same retesting frequencies for liquids and solids would mean relatively small quantities of liquids being retested often or relatively large volumes of solids becoming exempt without retesting.

Larger amounts of waste have the potential of greater environmental risk than smaller amounts. Therefore, we believe it is reasonable to require generators of larger waste streams to retest more frequently than generators of smaller waste streams. We would require testing at particular time intervals throughout the year, rather than allowing a generator to choose when such tests would be conducted. We do not want to provide a flexibility to generators that they could use to ''game the system,'' that is, choose most favorable sampling times within a calendar year. The development of these particular volume thresholds and their testing frequency is described in a background document to this notice (*see Background Document on Retesting Frequency,* U.S. EPA, July 1999).

Retesting frequency might also vary depending upon whether the generator seeking exemption is a small business. Small businesses and small generators are not necessarily the same '' small businesses, particularly those potentially affected by this exemption, are typically characterized by the number of employees at a firm (less frequently by the firm's annual receipts). To the extent that small businesses are not small generators, diminished retesting frequency based on smaller annual volumes would not apply. In order to reduce burden on small businesses, EPA could also consider reducing testing frequency for small business regardless of whether they produce comparatively small or large volumes of waste. Such reduced requirements would still need to ensure that the generator continues to be

accountable for compliance with the exemption levels.

Suggestions were also made that the retesting frequency be established based either on the variability of the waste stream or on the amount of difference between the exemption levels and the concentrations detected in the waste. Alternatively, retesting could be required after the production of a set amount of waste rather than based on elapsed time. We believe that such alternatives could be made workable for this exemption, but would certainly be more involved. As far as identifying which chemicals to retest, we have relied on the observed concentrations in the waste stream to suggest that chemicals below one-tenth of the exemption level do not require retesting. (See Section XI.A.1 of this preamble).

In the 1995 HWIR proposal, we proposed that the frequency of retesting would diminish over time. In today's notice, however, the frequency remains the same. Instead of diminishing the testing frequency, we would require retesting for those chemicals that are within an order of magnitude (above one-tenth) of the exemption levels. We believe this formulation will help reduce the burden of retesting and focus on those chemicals that are most likely to exceed the exemption levels due to waste stream variability. We request comment on these retesting provisions and particularly on whether retesting frequency should be diminished because of lower annual volumes or less variability in the waste stream. EPA also requests comments on whether to reduce testing frequency for generators who are small businesses that may or may not generate large annual volumes of waste.

3. *If the process generating my waste stream changes, would I have to retest?* If a significant process change occurs, then you would have to retest the waste stream. A significant process change is one that has the potential to change the exempt status of the HWIR waste. Establishing retesting for process change is consistent with other EPA guidance and regulation (examples include recommendations within our Ash Sampling Guidance, July 1995 and within the LDR program as discussed at 51 FR 40597). We request comment on whether to require retesting after a significant process change.

B. What Would Happen If My Waste Stream No Longer Meets the Exemption Levels?

If your waste stream no longer meets the HWIR exemption levels, it would no longer be exempt under this regulatory provision and would be a hazardous waste, subject to all hazardous waste management requirements. Once the waste is determined to be hazardous, it would remain hazardous until the waste stream met the exemption levels and the notification package requirements were fulfilled again. Compliance with HWIR exemption levels would be determined from the last available test data or from the latest sample taken from the waste in question. Testing which shows chemical concentration levels above exemption levels would not affect wastes previously generated under a valid claim of exemption.

One issue is whether there should be additional requirements if a wastestream loses its HWIR exempt status because it no longer meets the exemption levels or does not meet one of the other conditions of the exemption. For example, should there be a mandatory waiting period before the exemption can be reinstated? Such a waiting period would give the overseeing agency a chance to inspect the documentation of the original exemption and would prevent a generator from exempting a wastestream shipment by shipment (instead of determining if the entire wastestream is clearly nonhazardous). We request comment on whether we should require such a waiting period or impose other requirements needed before a waste stream can regain its exempt status.

C. What Records Would I Have To Maintain On-Site and for How Long?

You would have to maintain, on-site, a copy of the notification package sent to the overseeing agency, and a copy of the waste sampling and analysis plan for as long as the HWIR exemption continues to be active, and for the three years that follow. You would also have to maintain a record of all test results for three years after each waste testing event occurs. In addition, you would be required to maintain any specific documentation relied on in making process knowledge determinations, such as the Material Data Safety Sheet (MSDS), product labels, or information provided by manufacturers of the processing equipment. You would have to be able to explain any process knowledge determinations if requested by the overseeing agency.

D. How Would the Overseeing Agency Access These Records?

You would be required to make all records relating to the HWIR exemption, including any information claimed as Confidential Business Information, immediately available to an overseeing agency during an inspection. In addition, you would have to provide a copy of the records directly to the overseeing agency within five business days of receiving a written request.

E. What Would Happen If the Information I Submitted in the Notification Package Changes?

If any of the information in your notification package changes, you would have to provide a revised package to the overseeing agency within 30 days of that change.

XII. What Would Be the Conditions and Requirements for the Landfill-Only HWIR Exemption?

A. Which Conditions and Requirements Would Be the Same for the Generic HWIR Exemption and the Landfill-Only HWIR Exemption?

The landfill-only HWIR exemption would include all the same implementation conditions and requirements as the generic HWIR exemption, including waste sampling and analysis plans, notification, follow-up testing and recordkeeping and reporting.

B. What Additional Conditions and Requirements Would I Have to Meet for the Landfill-Only HWIR Exemption?

Because the exemption levels for the landfill-only HWIR exemption would be conditioned on disposal of this waste in a landfill, we believe that additional conditions and requirements are needed to ensure that the waste arrives at the landfill in a timely manner. The landfill-only exemption levels could not be considered protective of other waste management scenarios (including storage in a waste pile, which was modeled separately). The following three additional conditions and requirements for the landfill-only exemption would help address these concerns.

(1) You would have to dispose of this waste in a landfill.

(2) You would not be allowed to place this waste on the land, prior to disposal in a landfill. We are concerned about the temporary placement of these wastes in waste piles or other such intermediate land-based destinations, because exemption levels for the landfill-only option (unlike the levels for the generic option) would not consider such risks. We are particularly concerned about the potential of significant releases of particulate releases to air, as well as releases through erosion and runoff, since risks from these pathways are either not applicable or significantly reduced for the landfill scenario, but could be considerable for other scenarios.

To ensure that the HWIR waste exempted under the landfill-only option is eventually disposed in a landfill, we are requesting comment on whether to restrict storage time of these wastes to one year. You would also only be allowed to store the waste in non-land-based units, such as tanks, containers or containment buildings. This storage requirement is similar to one imposed on restricted wastes under the LDR program (40 CFR 268.50). 40 CFR 268.50(b) allows waste handlers to store restricted wastes for up to one year, unless EPA demonstrates that such storage is not solely for the purpose of accumulation for proper recovery, treatment, or disposal.

(3) You would have to track the arrival of your HWIR exempt waste at a landfill, and keep records of the shipments. Since the exemption levels for the landfill-only HWIR exemption would be based solely on assessing risks associated with disposal of this waste in a landfill, we want to ensure that the waste is, in fact, disposed at such a destination in a timely manner. We are asking for comment on three alternatives for tracking the landfill-only exempted waste.

Under the first alternative, you would have to directly notify the designated landfill of the shipment of landfill-only HWIR exempt waste. Specifically, this notification would include the date of shipment, the carrier(s) used, the destination facility, and volume and general description of the waste. This notification does not need to accompany the waste, since you notify the disposal facility directly.

You should receive a certification from the landfill operator that the waste arrived. You would have to keep a copy of this certification for three years. We also request comment on whether to require the destination landfill owner/operator to keep copies of this certification for three years as well. If you have not received a certification that the waste shipment arrived at the landfill 45 days after the date of shipment, then you would have to report this to the overseeing agency. If the waste has not reached the landfill within 60 days after the date of shipment, then on the 61st day, the waste stream would not be exempt from RCRA Subtitle C and is now a hazardous waste. You (the generator), as the person identified on the HWIR notification form, would be the generator of this hazardous waste and must comply with 40 CFR Part 262.

A second alternative, which we would like to receive comment on, would use the existing manifest system to track the conditionally exempt HWIR waste. The uniform hazardous waste manifest (40 CFR 262.20 and 49 CFR 172.205) is prepared and signed by the waste generator and accompanies the waste shipment as it moves among the waste carriers, until it reaches the designated facility that is permitted to receive the waste. The receiving facility must sign the manifest and return it to the hazardous waste generator. The generator, carrier(s), and receiving facility must retain copies of the signed manifests for three years. This cradle-to-grave tracking system is intended to ensure that hazardous waste is properly managed and to allow generators and their overseeing agencies the ability to track their hazardous wastes.

However, we are concerned that requiring nonhazardous materials transporters and waste management facilities to comply with manifest requirements could create considerable burden for nonhazardous facilities that become subject to these requirements. Furthermore, in many States, regulations prohibit Subtitle D facilities from receiving manifested wastes, and current federal regulations limit the use of the manifest to handlers that have EPA RCRA identification numbers.

On the other hand, we are planning in a separate action to propose revisions to the Uniform Hazardous Waste Manifest regulations in response to many requests for a streamlined, up-to-date, and less burdensome hazardous waste tracking system. Under the proposed revisions to the existing manifest system, we are developing a standard manifest form with fewer State optional boxes and are proposing to automate the manifest paperwork. Therefore, although we are not proposing to require uniform hazardous waste manifest tracking, we recognize that the revised manifest system might be perceived by industry and the states as a less burdensome alternative than creating an entirely new tracking system for HWIR exempt wastes. We request comment on using the revised manifest system for HWIR exempt wastes.

Under a third alternative, which we would like to receive comment on, we considered using Department of Transportation (DOT) shipping papers (49 CFR 173 Subpart C) to track the waste. Under this option, the shipping papers would need to include additional information, including the date of the shipment, the carrier used, and the destination facility. The generator would be required to provide the transporter with a copy of the shipping papers, which would identify the destination facility. The initial transporter, and any subsequent transporters, would be required to return to you a copy of each shipping paper, with a notation indicating the identification of the disposal facility (and/or the subsequent transporter). There would be no record keeping requirements placed upon the transporter or disposal facility, however, you would be required to keep copies of these records for three years.

However, the representatives from DOT were uncomfortable with this option for a number of reasons. First, although it serves to reduce burden on the landfill owner/operator, it increases the burden on the transporter in terms of having to send copies to generators with each change of custody. In addition, some wastes would fall out of DOT's jurisdiction without manifest coverage. DOT regulates ''hazardous materials,'' and waste accompanied by a hazardous waste manifests are automatically defined as a hazardous material. If the manifest is no longer required, then some wastes would no longer meet the definition of hazardous material. Therefore, we believe that the benefits provided by this option might be outweighed by the complexity of implementation. However, we would be interested in receiving public comment on this notion of using shipping papers or other alternative documents to track HWIR exempt wastes.

Regardless of which option we pursue, interstate transport of HWIR wastes would be an issue. If your State were to adopt an HWIR exemption, your HWIR waste would be nonhazardous only within your State or other States with the HWIR exemption. Thus, HWIR exempt wastes shipped to or through a State where the HWIR exemption had not been adopted would have to comply with the applicable hazardous waste requirements. Commentors to the 1995 HWIR proposal remarked on this patchwork of State programs as an important HWIR issue, but offered little way of specific guidance or suggestions for resolving this issue. We request further comment on this issue in today's notice.

XIII. What Would Happen if I Do Not Comply With the Conditions and the Requirements of the HWIR Exemption?

A. What Is the Difference Between an HWIR Condition and a Requirement?

A condition is an obligation you or your waste must meet in order for your waste to become and to remain exempt from hazardous waste regulations. If a condition is not fulfilled, then the waste is hazardous and subject to RCRA Subtitle C requirements. A requirement is an obligation whose violation would not affect the exempt status of the HWIR

waste, but would be a violation under RCRA.

B. What Are the Conditions for the Two HWIR Options, and What Would Happen if I Do Not Meet Them?

We are considering three conditions for meeting the generic HWIR waste exemption: (1) meeting the appropriate HWIR exemption levels (2) testing and retesting of the waste, which documents that exemption levels have been met; and (3) notification to the overseeing agency that you are managing the waste as exempt. The landfill-only alternative has four conditions: (1) meeting the appropriate HWIR exemption levels (2) testing and retesting of the waste, which documents that exemption levels have been met; (3) notification to the overseeing agency that you are managing the waste as exempt; and (4) waste arrival at the landfill facility within the 60 day time period.

Failure to meet any of these conditions would have the effect of rendering the waste back into regulation under RCRA Subtitle C. For example, under the landfill-only alternative, if a waste no longer met the exemption levels, or if the overseeing agency was not properly notified, or if the required testing was not performed, or if the waste did not arrive at the designated landfill within 60 days of shipment, then the waste stream would be considered hazardous and subject to all provisions of RCRA Subtitle C.

C. What Would HWIR Tracking Requirements Be, and What Would Happen if I Do Not Meet Them?

The HWIR tracking requirements would only apply to waste exempted under the landfill-only alternative. HWIR waste tracking requirements would be imposed on both generators and landfill operators.

As discussed in Section XII.B of this preamble, HWIR waste generators would have to notify the designated landfill of the shipment of conditionally exempt HWIR waste. The landfill operators receiving the waste must certify in writing to the generator confirming that the waste arrived at the landfill. The HWIR generator must keep copies of these records for three years from the shipment date, and we are requesting comment on whether the landfill operator must also keep copies of these records.

These tracking requirements would be under the authority of Sections 3007 and 2002 of RCRA Subtitle C and therefore are not conditions of the exemption. Section 3007 gives us the authority to compel anyone who generates, stores, treats, transports, disposes of or otherwise handles or has handled hazardous wastes to ''furnish information related to such wastes'' and make such information available to the government for ''the purposes of...enforcing the provisions of this chapter.'' Section 2002 gives the Administrator the authority to promulgate such regulations as are necessary to carry out the functions of the statute. Failure to comply with these tracking requirements would not affect the exempt status of the waste, but the landfill's failure to send back the certification would constitute a violation of RCRA.

Although the paperwork that tracks the arrival of the waste shipment at the landfill is a requirement, the arrival of the waste at the landfill within 60 days would be a condition. Thus if the waste arrived at the landfill within 60 days, but the landfill did not send back the certification of arrival, the waste would maintain its exempt status. (Although, as noted above, the landfill's failure to send back the certification would be a violation of RCRA). However, if the waste did not arrive at the landfill within 60 days of shipment, it would lose its exempt status and would be subject to all RCRA Subtitle C requirements.

XIV. What Might the Regulatory Language for the HWIR Exemption Look Like?

Below is draft language that shows what the HWIR exemption regulatory language might look like. As explained in Section XVII, , we are not proposing the HWIR exemption because of technical difficulties in developing chemical-specific exemption levels from the model. Before we would go final with an HWIR exemption, we would first publish an HWIR proposal that would include specific exemption levels and give the public an opportunity to comment. We are including this draft language for discussion to help you give us more targeted comments on the implementation provisions that we have discussed in previous preamble sections.

Purpose and Scope of the HWIR Exemption

A. What Is the Purpose of This Exemption?

(1) The HWIR exemption outlines the conditions and procedures that a facility can use to exempt a listed hazardous waste from the requirements of 40 CFR Parts 262–266, 270, and under certain circumstances, also from 40 CFR Part 268. A waste may be exempted when—preferably through pollution prevention or otherwise through treatment—the chemicals in the waste are at or below the exemption levels listed in Table 2.

(2) The rule sets exemption levels for two disposal alternatives. One allows unrestricted management of exempted wastes. The other requires exempted wastes be disposed only in a landfill.

B. What Is the Scope of This Exemption?

(1) Wastes meeting all requirements of the HWIR exemption are exempt from all requirements of 40 CFR Parts 262–266 and 270.

(2) Wastes meeting the requirements described in Section are not subject to the land disposal restrictions of 40 CFR Part 268.

(3) Wastes containing a chemical listed in Table 2 for which there is no exemption level in Table 3 are ineligible for this exemption.

C. What Definitions Apply?

Chemicals reasonably expected to be present means:

(1) Chemicals identified as the basis for listing the waste you wish to exempt. (For F and K listed waste, these chemicals are identified in Appendix VII of 40 CFR Part 261. For P and U listed waste, these are chemicals are found in 40 CFR 261.33),

(2) Chemicals listed in the table ''Treatment Standards for Hazardous Wastes'' contained in 40 CFR 268.40 as regulated hazardous chemicals for land disposal restriction (LDR) treatment of the waste,

(3) Chemicals detected in any previous analysis of the same waste,

(4) Chemicals introduced into the process that generates the waste, and

(5) Chemicals that are byproducts of the process that generates the waste.

Overseeing agency means the state or EPA regional authority that administers the exemption.

Waste form means at the point of exemption, the waste form is liquid, semi-solid, or solid, as defined below (for the purposes of the HWIR exemption only):

(1) *Liquid* means a waste contains total suspended solids less than 1% by weight.

(2) *Semi-solid* means a waste contains total suspended solids of 1% or more by weight but no more than 30% by weight.

(3) *Solid* means a waste contains total suspended solids more than 30% by weight.

Obtaining an Exemption

D. What Steps Must I Follow To Establish My Waste as Exempt?

You must take the following steps to establish that your waste meets the requirements of the HWIR exemption:

(1) Determine whether your waste is reasonably expected to contain any chemical listed in Table 2, using the criteria described in Section XIV.E.

Note: If your waste is reasonably expected to contain any chemical listed in Table 2 for which there is no exemption level in Table 3, your waste cannot be exempt under the HWIR exemption even if you do not detect the chemical.

(2) Determine the form of your waste (liquid, semi-solid, or solid) and under which regulatory alternative (unrestricted management or landfill-only) you will be claiming the exemption (see Section XIV.F).

(3) Determine the concentration of each Appendix X chemical reasonably expected to be present in your waste (see Sections XIV.G, H, and I).

(4) Determine whether the concentrations of all the Appendix X chemicals in your waste are at or below the exemption levels established for your waste form and disposal alternative (see Section XIV.J).

(5) Notify the overseeing agency that you are claiming an exemption under the HWIR exemption for your waste (see Section XIV.K).

(6) For the landfill-only alternative, notify the receiving landfill (see Section XIV.M).

E. What Wastes Are Eligible for this Exemption?

To be eligible for this exemption, your waste must meet the following conditions:

(1) Your waste must exhibit none of the characteristics of hazardous waste set out in subpart C of 40 CFR Part 261. If your waste does exhibit a hazardous waste characteristic, it must be de-characterized before it can be exempt.

(2) Your waste must meet one or more of the following descriptions:

(a) Any listed hazardous waste described in 40 CFR 261.31 (non-specific sources), 40 CFR 261.32 (specific sources), and 40 CFR 261.33 (discarded commercial chemical products).

(b) Any mixture of a listed hazardous waste with a solid waste under 40 CFR 261.3(a)(2)(iii) or (iv).

(c) Any waste derived from the treating, storing, or disposing of a listed hazardous waste under 40 CFR 261.3(c)(2)(i).

(d) Any media or debris contaminated with a listed hazardous waste, a mixture containing a listed hazardous waste, or a waste derived from a listed hazardous waste.

(3) All chemicals reasonably expected to be present in your waste must have exemption levels listed in Table 2, and be at or below those exemption levels. Chemicals reasonably expected to be present in your waste are those chemicals in Table 3 that meeting the following:

(a) Chemicals identified as the basis for listing the waste you wish to exempt. (For F and K listed waste, these chemicals are identified in Appendix VII of 40 CFR Part 261. For P and U listed waste, these are chemicals are found in 40 CFR 261.33).

(b) Chemicals listed in the table ''Treatment Standards for Hazardous Wastes'' contained in 40 CFR 268.40 as regulated hazardous chemicals for land disposal restriction (LDR) treatment of the waste.

(c) Chemicals detected in any previous analysis of the same waste.

(d) Chemicals introduced into the process that generates the waste.

(e) Chemicals that are byproducts of the process that generates the waste.

F. What Chemical Concentration Levels Must My Waste Meet To Become Exempt?

To become exempt your waste must meet the chemical concentration levels specified in Table 3. These exemption levels depend on the form of your waste (liquid, semi-solid, or solid) and the type of exemption you intend to pursue (unrestricted management or landfill only).

(1) To use the unrestricted-management alternative, the chemicals in your waste must be at or below the exemption levels in Table 3 for unrestricted management. Under this alternative, you must determine your waste form and meet the exemption level for that form. The waste form depends on the total suspended solids (TSS) in the waste (see definitions, Section XIV.C):

If your waste contains TSS in a concentration of	Then it is defined as a
Less than 1%	Liquid.
Between 1% and 30% ..	Semi-solid.
Greater than 30%	Solid.

(2) To use the landfill-only alternative then the chemicals in your waste must be at or below the exemption levels in Table 3 for landfill only.

G. For Which Chemicals Must I Test in My Waste?

(1) You must test your waste for each chemical reasonably expected to be present in your waste, as identified in Section XIV.E.

(2) For chemicals listed in Table 2 other than those reasonably expected to be present in your waste, you may either test for any such chemical or use your knowledge of the production process that generated the waste to determine that it is not present.

H. At What Point Must I Sample My Waste?

You may sample your waste at any point between its point of generation and its point of disposal. However, your waste will be subject to land disposal restrictions in 40 CFR Part 268 unless your waste meets all applicable concentration levels at its point of generation.

I. How Must I Sample and Analyze My Waste?

(1) For each waste you seek to exempt you must develop and follow a written plan for sampling and analyzing wastes. The plan must contain the following:

(a) The chemicals for which you will analyze each waste and the rationale for choosing those chemicals.

(b) Your methods for collecting a representative sample of the waste to be analyzed.

(c) Your preparation and test methods for analyzing these chemicals.

(d) Sampling procedures and locations for characterizing the waste stream.

(2) You must analyze at least 4 samples. You must also document the results from all samples analyzed.

J. What Must My Analysis Show?

(1) For every chemical tested, each sample must show that the total concentration in the waste is at or below the exemption level appropriate to your waste form and type of exemption.

(2) You must document your ability to analyze a sample spiked at or below the exemption level. Such documentation would consist of analytical results from a sample spiked at or below exemption level concentrations.

K. What Information Must I Submit to the Overseeing Agency?

Before managing any waste as exempt under the HWIR exemption, you must send a notice to the overseeing agency by certified mail or other mail service that confirms delivery in writing. This notice of your exemption claim must include all of the following:

(1) Your facility's name, address, and RCRA ID number.

(2) The applicable EPA hazardous waste code of your exempted waste and the narrative description associated with the listing from subpart D of 40 CFR Part 261.

(3) A brief, general description of how you manufactured, treated, or otherwise produced the waste.

(4) An estimate of the annual quantities of the exempted waste.

(5) A statement that you are claiming the HWIR exemption for the waste.

(6) A certification—signed by you or your authorized representative—that the information in your notice is true, accurate, and complete.

L. When Does the Exemption Take Effect?

The exemption—whether unrestricted management or landfill only—takes effect when you receive written confirmation of delivery to the overseeing agency. At that time you may begin managing your waste under this exemption.

M. Must I Track My Waste Exempted Under the HWIR Exemption?

(1) Waste meeting the exemption levels for unrestricted management require no tracking.

(2) For waste meeting the exemption levels for landfill-only:

(a) You must send written notice to the landfill receiving your waste and include the following:

(i) The date of the shipment.

(ii) The volume and form of the waste.

(iii) A general description of the exempt waste.

(iv) The shipper(s) used to transport the waste.

(v) A signed certification that your waste meets the exemption levels for landfill-only.

(b) You must receive a certification from the landfill owner or operator that the waste shipment reached the landfill within 60 days of shipment. If you do not receive this certification within 45 days of the shipment date, you must notify the overseeing agency in writing that you have not received the certification.

(c) You must keep a copy of the notification you sent to the landfill and a copy of the certification you received from the landfill (and/or the notification you sent to the overseeing agency that you did not receive the certification from the landfill) for three years.

(d) If your waste does not arrive at the landfill within 60 days of shipment, the waste that you claimed as exempt is no longer exempt on the 61st day and is now a hazardous waste. You, as the person identified on the HWIR notification form, are the generator of this hazardous waste and must comply with 40 CFR Part 262.

N. Must my waste meet 40 CFR Part 268—Land Disposal Requirements?

Your waste must meet all applicable requirements in 40 CFR Part 268, unless each waste sample is at or below the exemption levels at the point of generation.

O. Where May I Dispose of My Exempt Waste?

(1) For the unrestricted management alternative, you may dispose of this waste in any destination that can legally accept nonhazardous waste.

(2) For the landfill-only alternative, you must dispose of this waste directly in a landfill licensed or permitted by the state or federal government under Subtitle C or D of RCRA. The waste must not be placed on the land before final disposal.

Maintaining an Exemption

P. What If the Information I Submitted Changes?

You must submit to the head of the overseeing agency any change in any information submitted as describe in Section XIV.K within 30 business days of learning of the change.

Q. What Retesting Must I Do?

(1) You must retest for all chemicals reasonably expected to be in your waste on the following schedule, based on waste form and annual quantity of the waste produced. However, you do not need to retest for the chemical if after twelve months of testing, your analysis has shown concentrations uniformly below one-tenth of the applicable exemption level.

If you generate the following annual quantity of liquid waste (tons):	Then you must retest
0–35,000	Every 12 months.
35,000–500,000	Every 6 months.
Over 500,000	Every 3 months.
If you generate the following annual quantity of semi-solid or solid waste (tons)	**Then you must retest**
0–2,000	Every 12 months.
2,000–10,000	Every 6 months.
Over 10,000	Every 3 months.

(2) You must follow a waste sampling and analysis plan meeting the requirements described in Section XIV.I for retesting.

(3) If at any time the process generating the exempt waste changes significantly, you must retest the waste for all chemicals reasonably expected to be present. A significant change is one that could affect the exempt status of the waste under consideration. For example, a change that adds new chemicals or increases chemical concentrations is a significant change.

R. What Records Must I Maintain On-Site, and for How Long?

You must keep records of the following in your files on-site for three years after the date of the relevant test:

(1) The waste sampling and analysis plans for initial testing (as described in Section XIV.I) and retesting (as described in Section XIV.Q).

(2) Results from the waste sampling and analysis including quality control analyses from initial testing or retesting.

(3) All volume determinations made to decide on the frequency of retesting as described in Section XIV.Q.

(4) Any information submitted to the overseeing agency either as part of the initial notice (see Section XIV.K) or for later changes (see Section XIV.P).

(5) Any specific documentation relied on in making process knowledge determinations, such as the Material Data Safety Sheet (MSDS), product labels, or information provided by manufacturers of the processing equipment.

(6) Documentation of compliance with the LDR requirements of 40 CFR 268.

(7) For the landfill-only alternative, notification that the waste was shipped to a landfill and certification that the waste shipment reached the landfill (see Section XIV.M).

Consequences of Not Meeting the Exemption

S. How Will the Overseeing Agency Verify an Exemption?

(1) The overseeing agency may conduct inspections and audits to verify your exemption claim. Such inspections could include sampling of the exempt waste stream. Exceedances of the exemption levels determined by single grab samples would be sufficient to demonstrate non-compliance with the requirements of the exemption.

(2) You must make all records relating to the exemption immediately available to the overseeing agency performing an inspection. You must provide a copy of the records to the overseeing agency within 5 business days of receiving a written request.

(3) You must be able to explain any process knowledge determinations if requested by the overseeing agency.

(4) In an enforcement action, the burden of proof to establish compliance

with the requirements of the HWIR exemption is on the person claiming the exemption.

T. What Is the Status of My Waste if I Don't Meet or Maintain the Exemption?

Failure to satisfy any of the exemption conditions [except those described in Sections XIV.M(2)(a)–XIV.M(2)(c)] voids the exemption and requires that you manage the exempted waste stream has hazardous waste.

Failure to satisfy the requirements described in Sections XIV.M(2)(a)–XIV.M(2)(c) for the landfill-only alternative (in other words, the tracking requirements) would not affect the exempt status of the waste, but would constitute a violation of RCRA.

TABLE 2.—APPENDIX X HWIR EXEMPTION CHEMICALS

Chemical name [alternate names]	CASRN	Note
A2123 [Ethanimidothioic acid, 2-(dimethylamino) -N-hydroxy-2-oxo-,methyl ester]	30558–43–1	
Acenaphthene	83–32–9	b
Acenaphthylene [Acenaphthalene]	208–96–8	b
Acetaldehyde [Ethanal]	75–07–0	
Acetone [2-Propanone]	67–64–1	
Acetonitrile [Ethanenitrile]	75–05–8	
Acetophenone	98–86–2	
2-Acetylaminofluorene [2-AAF]	53–96–3	b
Acrolein [2-Propenal]	107–02–8	
Acrylamide [Propenaminde]	79–06–1	
Acrylic acid	79–10–7	
Acrylonitrile [2-Propenenitrile]	107–13–1	
Aldicarb	116–06–3	
Aldicarb sulfone	1646–88–4	
Aldrin	309–00–2	
Allyl alcohol	107–18–6	
Allyl chloride [3-Chloropropylene] [3-Chloropropene]	107–05–1	
4-Aminobiphenyl	92–67–1	
5-Aminomethyl-3-isoxazolol [Muscimol]	2763–96–4	
4-Aminopyridine	504–24–5	b
Amitrole	61–82–5	
Ammonium picrate	131–74–8	
Aniline	62–53–3	
Anthracene	120–12–7	b
Antimony [Antimony, total]	7440–36–0	b, c
Aramite	140–57–8	
Arsenic [Arsenic, total]	7440–38–2	b, c
Auramine	492–80–8	
Azaserine	115–02–6	
Barban	101–27–9	
Barium [Barium, total]	7440–39–3	b, c
Bendiocarb	22781–23–3	
Bendiocarb phenol	22961–82–6	
Benomyl	17804–35–2	
Benz[c]acridine	225–51–4	b
Benz[a]anthracene	56–55–3	b
Benzene	71–43–2	
Benzenesulfonyl chloride	98–09–9	
Benzidine	92–87–5	
Benzo[b]fluoranthene	205–99–2	b
Benzo[j]fluoranthene	205–82–3	b
Benzo[k]fluoranthene	207–08–9	b
Benzo[g,h,i]perylene	191–24–2	b
Benzo[a]pyrene	50–32–8	b
Benzyl alcohol	100–51–6	
Benzyl chloride	100–44–7	
Beryllium [Beryllium, total]	7440–41–7	b, c
Bromoacetone	598–31–2	
Bromodichloromethane [Dichlorobromomethane]	75–27–4	b
Bromoform [Tribromomethane]	75–25–2	b
Bromomethane [Methyl bromide]	74–83–9	b
4-Bromophenyl phenyl ether [p-Bromodiphenyl ether]	101–55–3	
Brucine [2,3-Dimethoxy strychnidin-10-one]	357–57–3	
n-Butyl alcohol [n-Butanol]	71–36–3	
Butylate	2008–41–5	
Butyl benzyl phthalate	85–68–7	b
Cadmium [Cadmium, total]	7440–43–9	b, c
Carbaryl	63–25–2	
Carbendazim	10605–21–7	
Carbofuran	1563–66–2	
Carbofuran phenol	1563–38–8	
Carbon disulfide	75–15–0	
Carbon tetrachloride	56–23–5	b

TABLE 2.—APPENDIX X HWIR EXEMPTION CHEMICALS—Continued

Chemical name [alternate names]	CASRN	Note
Carbosulfan	55285–14–8	
Chlorambucil	305–03–3	
Chlordane [Chlordane, alpha and gamma isomers]	57–74–9	a
Chlornaphazin	494–03–1	
Chloroacetaldehyde	107–20–0	
4-Chloroaniline [p-Chloroaniline]	106–47–8	
Chlorobenzene [Monochlorobenzene]	108–90–7	b
Chlorobenzilate	510–15–6	
p-Chloro-m-cresol	59–50–7	b
Chloroethane [Ethyl chloride]	75–00–3	b
bis-(2-Chloroethoxy) methane [Dichloromethoxy ethane]	111–91–1	
bis-(2-Chloroethyl) ether [Dichloroethyl ether] [1,1′-Oxybis(2-chloroethane)]	111–44–4	b
Chloroform [Trichloromethane]	67–66–3	b
bis-(2-Chloroisopropyl) ether [2,2′-Oxybis(1-chloropropane)] [Bis-(2-Chloro-1-methylethyl) ether]	108–60–1	b
Chloromethane [Methyl chloride]	74–87–3	b
bis-(Chloromethyl) ether [Dichloromethyl ether]	542–88–1	b
2-Chloronaphthalene [beta-Chloronaphthalene]	91–58–7	b
2-Chlorophenol [o-Chlorophenol]	95–57–8	b
4-Chlorophenyl phenyl ether [p-Chlorodiphenyl ether]	7005–72–3	b
1-(o-Chlorophenyl) thiourea	5344–82–1	
Chloroprene [2-Chloro-1,3-butadiene]	126–99–8	
3-Chloropropionitrile	542–76–7	
4-Chloro-o-toluidine hydrochloride	3165–93–3	
Chromium [Chromium, total]	7440–47–3	b, c
Chrysene	218–01–9	b
Citrus red No. 2	6358–53–8	
Cobalt [Cobalt, total]	7440–48–4	e
Copper [Copper, total]	7440–50–8	c
Copper dimethyldithiocarbamate	137–29–1	
o-Cresol [2-Methyl phenol]	95–48–7	a
—Cresol [3-Methyl phenol]	108–39–4	a
p-Cresol [4-Methyl phenol]	106–44–5	a
Crotonaldehyde [trans-2-Butenal] [beta-Methylacrolein]	4170–30–3	
Cumene [Isopropyl benzene]	98–82–8	
—Cumenyl methylcarbamate	64–00–6	
Cyanides, amenable	57–12–5	b, d
Cyanides, total	57–12–5	b, d
Cycasin	14901–08–7	
Cycloate	1134–23–2	
Cyclohexane	110–82–7	
Cyclohexanone	108–94–1	
2-Cyclohexyl-4,6-dinitrophenol	131–89–5	b
Cyclophosphamide	50–18–0	
2,4–D [2,4-Dichlorophenoxyacetic acid]	94–75–7	d
Daunomycin	20830–81–3	
Dazomet	533–74–4	
o,p′-DDD	53–19–0	a
p,p′-DDD	72–54–8	a
o,p′-DDE [o,p′ TDE]	3424–82–6	a
p,p′-DDE [p,p′-TDE]	72–55–9	a
o,p′-DDT	789–02–6	a
p,p′-DDT	50–29–3	a
Diallate	2303–16–4	
Dibenz[a,h]acridine	226–36–8	b
Dibenz[a,j]acridine	224–42–0	b
Dibenz[a,h]anthracene	53–70–3	b
7H-Dibenzo[c,g]carbazole	194–59–2	b
Dibenzofuran	132–64–9	
Dibenzo[a,e]pyrene	192–65–4	b
Dibenzo[a,h]pyrene	189–64–0	b
Dibenzo[a,i]pyrene	189–55–9	b
Dibromochloromethane [Chlorodibromomethane]	124–48–1	b
1,2-Dibromo-3-chloropropane	96–12–8	
Di-n-butyl phthalate	84–74–2	b
1,2-Dichlorobenzene [o-Dichlorobenzene]	95–50–1	a, b
1,3-Dichlorobenzene [m-Dichlorobenzene]	541–73–1	a, b
1,4-Dichlorobenzene [p-Dichlorobenzene]	106–46–7	a, b
3,3′-Dichlorobenzidine	91–94–1	
cis-1,4-dichloro-2-butene	1476–11–5	a
trans-1-4-Dichloro-2-butene	110–57–6	a
Dichlorodifluoromethane [CFC–12]	75–71–8	b
1,1-Dichloroethane [Ethylidene dichloride]	75–34–3	b

TABLE 2.—APPENDIX X HWIR EXEMPTION CHEMICALS—Continued

Chemical name [alternate names]	CASRN	Note
1,2-Dichloroethane [Ethylene dichloride]	107–06–2	b
1,1-Dichloroethylene [Vinylidene chloride]	75–35–4	b
cis-1,2-Dichloroethylene	156–59–2	a, b
trans-1,2-Dichloroethylene	156–60–5	a, b
2,2′-Dichloroisopropyl ether [2,2′-Oxybis(2-chloropropane)]	39638–32–9	b
2,4-Dichlorophenol 120–83–2 b 2,6–Dichlorophenol	87–65–0	b
1,1-Dichloropropane [Propylidene chloride]	78–99–9	a, b
1,2-Dichloropropane [Propylene dichloride]	78–87–5	a, b
1,3-Dichloropropanol	26545–73–3	a, b
Dichloropropene [Dichloropropylene] [Dichloro-1-Propene]	26952–23–8	b
cis-1,3-Dichloropropene [cis-1,3-Dichloropropylene]	10061–01–5	a, b
trans-1,3-Dichloropropene [trans-1,3-Dichloropropylene]	10061–02–6	a, b
Dieldrin	60–57–1	
1,2,3,4-Diepoxybutane [2,2′-Bioxirane]	1464–53–5	
Diethylene glycol, dicarbamate	5952–26–1	
O,O-Diethyl-S-methyl dithiophosphate	3288–58–2	b
Diethyl-p-nitrophenyl phosphate	311–45–5	
Diethyl phthalate	84–66–2	b
Diethylstilbestrol	56–53–1	
Dihydrosafrole	94–58–6	
Dimethoate [O,O-Dimethyl S-methylcarbamoylmethyl phosphorodithioate]	60–51–5	b
3,3′-Dimethoxybenzidine	119–90–4	
Dimethylamine [N-Methyl methanamine]	124–40–3	
p-Dimethylaminoazobenzene [4-Dimethylaminoazobenzene]	60–11–7	
7,12-Dimethylbenz[a]anthracene	57–97–6	b
3,3′-Dimethylbenzidine	119–93–7	
2,4-Dimethyl phenol	105–67–9	b
Dimethyl phthalate	131–11–3	b
Dimethyl sulfate	77–78–1	
Dimetilan	644–64–4	
1,3-Dinitrobenzene [m-Dinitrobenzene]	99–65–0	b
1,4-Dinitrobenzene [p-Dinitrobenzene]	100–25–4	b
4,6-Dinitro-o-cresol [4,6-Dinitro-2-methyl phenol]	534–52–1	d
2,4-Dinitrophenol	51–28–5	b
2,4-Dinitrotoluene	121–14–2	
2,6-Dinitrotoluene	606–20–2	
Dinoseb [2-sec-Butyl-4,6-dinitrophenol]	88–85–7	b
Di-n-octyl phthalate	117–84–0	b
1,4-Dioxane [1,4-Diethylene dioxide]	123–91–1	
Diphenylamine [N,N-Diphenylamine]	122–39–4	
1,2-Diphenylhydrazine	122–66–7	
Di-n-propylamine [Dipropylamine]	142–84–7	
Disulfiram [Tetraethylthiuram disulfide]	97–77–8	
Disulfoton [O,O-Diethyl S-(2-(ethylthio)ethyl)phosphorodithioate]	298–04–4	b
Dithiobiuret	541–53–7	
Endosulfan I [alpha-Endosulfan]	959–98–8	a
Endosulfan II [beta-Endosulfan]	33213–65–9	a
Endosulfan sulfate	1031–07–8	
Endothall	145–73–3	
Endrin	72–20–8	
Endrin aldehyde	7421–93–4	b
Endrin ketone	53494–70–5	b
Epichlorohydrin [1-Chloro-2,3-epoxypropane]	106–89–8	
Epinephrine	51–43–4	
2-Ethoxyethanol [Ethylene glycol monoethyl ether] [Cellosolve]	110–80–5	b
Ethyl acetate	141–78–6	
Ethyl acrylate	140–88–5	
Ethyl benzene	100–41–4	
Ethyl carbamate [Urethane] [Carbamic acid, ethyl ester]	51–79–6	
S-Ethyl dipropylthiocarbamate [EPTC]	759–94–4	
Ethylenebisdithiocarbamic acid	111–54–6	d
Ethylene dibromide [1,2-Dibromoethane]	106–93–4	
Ethylene oxide	75–21–8	
Ethylene thiourea [2-Imidazolidinethione]	96–45–7	
Ethyl ether [Ethane 1,1′ oxybis]	60–29–7	
bis-(2-Ethylhexyl) phthalate [Di-2-ethylhexyl phthalate]	117–81–7	b
Ethyl methacrylate	97–63–2	
Ethyl methanesulfonate	62–50–0	
Ethyl Ziram	14324–55–1	
Famphur	52–85–7	
Ferbam	14484–64–1	
2-Fluoracetamide	640–19–7	

TABLE 2.—APPENDIX X HWIR EXEMPTION CHEMICALS—Continued

Chemical name [alternate names]	CASRN	Note
Fluoranthene	206–44–0	b
Fluorene	86–73–7	b
Fluoride	16984–48–8	c
Fluoroacetic acid, sodium salt [Sodium fluoroacetate]	62–74–8	
Formaldehyde	50–00–0	
Formetanate hydrochloride	23422–53–9	
Formic Acid	64–18–6	
Formparanate	17702–57–7	
Furan	110–00–9	
Furfural [2-Furancarboxaldehyde]	98–01–1	
Heptachlor	76–44–8	
Heptachlor epoxide, alpha, beta, and gamma isomers	1024–57–3	a
1,2,3,4,6,7,8-Heptachlorodibenzo-p-dioxin	35822–46–9	a
1,2,3,4,6,7,8-Heptachlorodibenzofuran	67562–39–4	a
1,2,3,4,7,8,9-Heptachlorodibenzofuran	55673–89–7	a
Hexachlorobenzene	118–74–1	b
Hexachloro-1,3-butadiene [Hexachlorobutadiene]	87–68–3	
alpha-Hexachlorocyclohexane [alpha-BHC]	319–84–6	a
beta-Hexachlorocyclohexane [beta-BHC]	319–85–7	a
delta-Hexachlorocyclohexane [delta-BHC]	319–86–8	a
gamma-Hexachlorocyclohexane [gamma-BHC] [Lindane]	58–89–9	a
Hexachlorocyclopentadiene	77–47–4	
1,2,3,4,7,8 Hexachlorodibenzo-p-dioxin	39227–28–6	a
1,2,3,6,7,8 Hexachlorodibenzo-p-dioxin	57653–85–7	a
1,2,3,7,8,9-Hexachlorodibenzo-p-dioxin	19408–74–3	a
1,2,3,4,7,8 Hexachlorodibenzofuran	70648–26–9	a
1,2,3,6,7,8 Hexachlorodibenzofuran	57117–44–9	a
1,2,3,7,8,9 Hexachlorodibenzofuran	72918–21–9	a
2,3,4,6,7,8-Hexachlorodibenzofuran	60851–34–5	a
Hexachloroethane	67–72–1	b
Hexachlorophene	70–30–4	
Hexachloropropene [Hexachloropropylene]	1888–71–7	
Hexaethyl tetraphosphate	757–58–4	
2-Hexanone	591–78–6	
Indeno[1,2,3-cd]pyrene	193–39–5	b
Iodomethane [Methyl iodide]	74–88–4	b
3-Iodo-2-propynyl N-butylcarbamate	55406–53–6	
Isobutyl alcohol [isobutanol]	78–83–1	
Isodrin	465–73–6	
Isolan [Isopropyl methyl pyrazolyl dimethylcarbamate]	119–38–0	
Isophorone	78–59–1	
Isosafrole	120–58–1	
Kepone [Chlordecone]	143–50–0	
Lasiocarpine	303–34–1	
Lead [Lead,total]	7439–92–1	b, c
Maleic hydrazide	123–33–1	
Malononitrile [Propanedinitrile]	109–77–3	
Manganese dimethyldithiocarbamate	15339–36–3	
Melphalan	148–82–3	
Mercury [Mercury, total]	7439–97–6	b, c
Metam Sodium	137–42–8	
Methacrylonitrile [2-Methyl-2-propenenitrile]	126–98–7	
Methanol [Methyl alcohol]	67–56–1	
Methapyrilene	91–80–5	
Methiocarb	2032–65–7	
Methomyl	16752–77–5	
Methoxychlor	72–43–5	
3-Methylcholanthrene	56–49–5	b
4-Methylene bis-(2-chloroaniline)	101–14–4	
Methylene bromide [Dibromomethane]	74–95–3	b
Methylene chloride [Dichloromethane]	75–09–2	b
Methyl ethyl ketone [2-Butanone] [MEK]	78–93–3	
Methyl isobutyl ketone [Hexone] [4-Methyl-2-pentanone]	108–10–1	
2-Methyllactonitrile [Acetone cyanohydrin]	75–86–5	
Methyl methacrylate	80–62–6	
Methyl methanesulfonate	66–27–3	
2-Methylnaphthalene	91–57–6	b
Methyl parathion [O,O-Dimethyl O-p-nitrophenyl phosphorothioate]	298–00–0	b
2-Methyl pyridine [alpha-Picoline] [2-Picoline]	109–06–8	b
Methylthiouracil	56–04–2	
Metolcarb	1129–41–5	
Mexacarbate	315–18–4	

TABLE 2.—APPENDIX X HWIR EXEMPTION CHEMICALS—Continued

Chemical name [alternate names]	CASRN	Note
Molinate	2212–67–1	
Naphthalene	91–20–3	
1,4-Naphthoquinone	130–15–4	
1-Naphthylamine [alpha-Naphthylamine]	134–32–7	
2-Naphthylamine [beta-Naphthylamine]	91–59–8	
1-Naphthyl-2-thiourea [alpha-Naphthylthiourea]	86–88–4	
Nickel [Nickel, total]	7440–02–0	b, c
Nicotine	54–11–5	d
2-Nitroaniline [o-Nitroaniline] [2-Nitrobenzenamine]	88–74–4	
3-Nitroaniline [m-Nitroaniline] [3-Nitrobenzenamine]	99–09–2	
4-Nitroaniline [p-Nitroaniline] [4-Nitrobenzenamine]	100–01–6	
Nitrobenzene	98–95–3	
Nitroglycerine	55–63–0	
2-Nitrophenol [o-Nitrophenol]	88–75–5	b
4-Nitrophenol [p-Nitrophenol]	100–02–7	b
2-Nitropropane	79–46–9	
4-Nitroquinoline-1-oxide	56–57–5	
N-Nitrosodi-n-butylamine	924–16–3	b
N-Nitrosodiethanolamine	1116–54–7	b
N-Nitrosodiethylamine	55–18–5	b
N-Nitrosodimethylamine	62–75–9	b
N-Nitrosodiphenylamine [Diphenylnitrosamine]	86–30–6	b
N-Nitrosodi-n-propylamine [Di-n-propylnitrosamine]	621–64–7	b
N-Nitroso-N-ethylurea	759–73–9	b
N-Nitroso-N-methylethylamine	10595–95–6	b
N-Nitroso-N-methylurea	684–93–5	b
N-Nitroso-N-methylurethane	615–53–2	b
N-Nitrosomethylvinylamine	4549–40–0	b
N-Nitrosomorpholine	59–89–2	b
N-Nitrosonornicotine	16543–55–8	b
N-Nitrosopiperidine	100–75–4	b
N-Nitrosopyrrolidine	930–55–2	b
N-Nitrososarcosine	13256–22–9	b
5-Nitro-o-toluidine [2-Methyl-5-nitroaniline]	99–55–8	
Octachlorodibenzo-p-dioxin [OCDD]	3268–87–9	a
Octachlorodibenzofuran [OCDF]	39001–02–0	a
Octamethylpyrophosphoramide	152–16–9	
Osmium	7440–04–2	c
Oxamyl	23135–22–0	
Paraldehyde	123–63–7	
Parathion [O,O-Diethyl O-p-nitrophenyl phosphorothioate]	56–38–2	b
Pebulate	1114–71–2	
Pentachlorobenzene	608–93–5	b
1,2,3,7,8-Pentachlorodibenzo-p-dioxin	40321–76–4	a
1,2,3,7,8-Pentachlorodibenzofuran	57117–41–6	a
2,3,4,7,8-Pentachlorodibenzofuran	57117–31–4	a
Pentachloroethane	76–01–7	b
Pentachloronitrobenzene [PCNB] [Quintobenzene] [Quintozene]	82–68–8	
Pentachlorophenol [PCP]	87–86–5	b, c
1,3-Pentadiene	504–60–9	
bis-(Pentamethylene) thiuram tetrasulfide	120–54–7	
Phenacetin	62–44–2	
Phenanthrene	85–01–8	b
Phenol	108–95–2	b
Phentermine [alpha,alpha-Dimethylphenethylamine]	122–09–8	
1,2-Phenylenediamine [o-Phenylenediamine]	95–54–5	a
1,3-Phenylenediamine [m-Phenylenediamine]	108–45–2	a
1,4-Phenylenediamine [p-Phenylenediamine]	106–50–3	a
Phenylthiourea	103–85–5	
Phorate [O,O-Diethyl S-(ethylthio)methyl phosphorodithioate]	298–02–2	b
o-Phthalic acid	88–99–3	
p-Phthalic acid [Terephthalic acid] [1,4-Benzenedicarboxylic acid]	100–21–0	
Physostigmine	57–47–6	
Physostigmine salicylate	57–64–7	
Polychlorinated biphenyls, total [PCBs, total]	1336–36–3	e
Potassium dimethyldithiocarbamate	128–03–0	
Potassium N-hydroxymethyl N-methyldithiocarbamate	51026–28–9	
Potassium N-methyldithiocarbamate	137–41–7	
Promecarb	2631–37–0	
Pronamide	23950–58–5	
Propanenitrile [Propionitrile] [Ethyl cyanide]	107–12–0	
1,3–Propane sultone	1120–71–4	

TABLE 2.—APPENDIX X HWIR EXEMPTION CHEMICALS—Continued

Chemical name [alternate names]	CASRN	Note
Propargyl alcohol [2-Propyn-1-ol]	107–19–7	
Propham	122–42–9	
Propoxur [Baygon] [2-(1-Methylethoxy)-phenol, methylcarbamate]	114–26–1	
n-Propyl amine [1-Propanamine]	107–10–8	
1,2–Propyleneimine [2-Methylaziridine]	75–55–8	
Propylthiouracil [6-Propyl-2-thiouracil]	51–52–5	
Prosulfocarb	52888–80–9	
Pyrene	129–00–0	b
Pyridine	110–86–1	b
Quinone [p-Benzoquinone]	106–51–4	
Reserpine	50–55–5	
Resorcinol [1,3-Benzenediol]	108–46–3	
Saccharin	81–07–2	d
Safrole	94–59–7	
Selenium [Selenium, total]	7782–49–2	b, c
Selenium, tetrakis(dimethyldithiocarbamate) [Selenium dimethyldithiocarbamate]	144–34–3	
Silver [Silver, total]	7440–22–4	b, c
Silvex [2,4,5-Trichlorophenoxypropionic acid] [2,4,5-TP]	93–72–1	b
Sodium azide	26628–22–8	
Sodium dibutyldithiocarbamate	136–30–1	
Sodium diethyldithiocarbamate	148–18–5	
Sodium dimethyldithiocarbamate	128–04–1	
Streptozotocin	18883–66–4	
Strychnine	57–24–9	d
Styrene [Vinyl benzene] [Phenylethylene]	100–42–5	
Sulfallate	95–06–7	
Sulfide	18496–25–8	c
Sulfotepp [Tetraethyldithiopyrophosphate]	3689–24–5	b
Tetrabutylthiuram disulfide	1634–02–2	
Tetramethylthiuram monosulfide [Bis-(dimethylthiocarbamoyl)sulfide]	97–74–5	
1,2,4,5-Tetrachlorobenzene	95–94–3	a, b
2,3,7,8-Tetrachlorodibenzo-p-dioxin [2,3,7,8–TCDD]	1746–01–6	a
2,3,7,8-Tetrachlorodibenzofuran [2,3,7,8–TCDF]	51207–31–9	a
1,1,1,2-Tetrachloroethane	630–20–6	a
1,1,2,2-Tetrachloroethane	79–34–5	a, b
Tetrachloroethylene [Perchloroethylene]	127–18–4	
2,3,4,6-Tetrachlorophenol	58–90–2	a, b, c
Tetrahydrofuran	109–99–9	
Tetranitromethane	509–14–8	
Thallium [Thallium, total]	7440–28–0	b, c
Thioacetamide	62–55–5	
Thiodicarb	59669–26–0	
Thiofanox	39196–18–4	
Thiomethanol [Methyl mercaptan] [Methanethiol]	74–93–1	
Thionazin [O,O,-Diethyl O-pyrazinyl phosphorothioate]	297–97–2	b
Thiophanate-methyl	23564–05–8	
Thiophenol [Benzenethiol]	108–98–5	
Thiosemicarbazide	79–19–6	
Thiourea	62–56–6	
Thiram [Thiuram] [Tetramethylthiuram disulfide]	137–26–8	
Tin [Tin, total]	7440–31–5	e
Tirpate	26419–73–8	
Toluene [Methylbenzene]	108–88–3	
2,4-Toluene diisocyanate	584–84–9	a
2,6-Toluene diisocyanate	91–08–7	a
2,4-Toluenediamine [2,4-Diaminotoluene] [Toluene-2,4-diamine]	95–80–7	a
2,6-Toluenediamine [2,6-Diaminotoluene]	823–40–5	a
3,4-Toluenediamine [3,4-Diaminotoluene]	496–72–0	a
o-Toluidine [2-Methylaniline]	95–53–4	c
p-Toluidine [4-Methylaniline]	106–49–0	
Toxaphene [Chlorinated camphene]	8001–35–2	
Triallate	2303–17–5	
2,4,6-Tribromophenol	118–79–6	
1,2,4-Trichlorobenzene	120–82–1	a, b
1,1,1-Trichloroethane [Methyl chloroform]	71–55–6	a, b
1,1,2-Trichloroethane [Vinyl trichloride]	79–00–5	a, b
Trichloroethylene	79–01–6	
Trichlorofluoromethane [Trichloromonofluoromethane] [CFC-11]	75–69–4	b
Trichloromethanethiol	75–70–7	
2,4,5-Trichlorophenol	95–95–4	a, b
2,4,6-Trichlorophenol	88–06–2	a, b
2,4,5-Trichlorophenoxyacetic acid [2,4,5,-T]	93–76–5	b

TABLE 2.—APPENDIX X HWIR EXEMPTION CHEMICALS—Continued

Chemical name [alternate names]	CASRN	Note
1,2,3-Trichloropropane	96–18–4	a
1,1,2-Trichloro-1,2,2-trifluoroethane [Freon 113]	76–13–1	b
Triethylamine	121–44–8	
O,O,O-Triethylphosphorothioate	126–68–1	b
1,3,5-Trinitrobenzene [sym-Trinitrobenzene]	99–35–4	
Tris-(1-azridinyl) phosphine sulfide	52–24–4	
Tris-(2,3 -dibromopropyl) phosphate	126–72–7	
Trypan blue	72–57–1	
Vanadium [Vanadium, total]	7440–62–2	c
Vernolate [Vernam]	1929–77–7	
Vinyl chloride [Chloroethylene] [Ethylene chloride]	75–01–4	
Vinyl acetate	108–05–4	
Warfarin	81–81–2	d
o-Xylene	95–47–6	a
m-Xylene	108–38–3	a
p-Xylene	106–42–3	a
Zinc [Zinc,total]	7440–66–6	c
Ziram	137–30–4	

(a) These chemicals are isomers that have been chosen to represent either mixtures of isomers or where isomers were not specified (e.g., ortho-, meta-, and para-Xylene are all isomers and therefore, represent Xylenes, isomers not specified). These chemicals may be used in industry as single isomers or as a mixture of isomers. While the CASRN for mixtures of isomers are not the same as those for the individual isomers, the mixtures are regulated by inclusion of these isomers on the list.

(b) These chemicals have been chosen to represent the various classes of chemicals that are regulated as ''multi-chemical classes'' under RCRA (e.g., Endrin aldehyde and Endrin ketone have been chosen as representatives of Endrin Metabolites, which is regulated under RCRA.) Other chemicals with this note specifically represent those ''multi-chemical classes'' that are regulated under RCRA using an ''N.O.S.'' designation. N.O.S. stands for ''Not Otherwise Specified'' (e.g., 2-Chloronaphthalene has been chosen to represent Chlorinated naphthalene, N.O.S.) For some chemicals all the isomers were already listed in RCRA regulations, for others only the commercially available isomers were listed.

(c) These chemicals have been chosen to represent specific RCRA-regulated chemical salts or compounds that cannot be measured directly. By analyzing for the chemicals listed with this footnote, the other RCRA-regulated chemicals are therefore covered (e.g., Arsenic acid, Arsenic Trioxide, and other arsenic compounds can be measured in wastes by measuring for Arsenic, total.)

(d) These chemicals have been chosen to represent RCRA-regulated ''groups'' of chemicals (e.g., salts) that are directly derived-from the chemical on the list (e.g., Nicotine salts are derived-from Nicotine.) The salts are typically converted back to the parent compound or a related compound during analysis of wastes. The individual salts can not typically be measured directly. All salts, esters, and other compounds that are measured by analyzing for this chemical are also regulated by this rule; i.e., one can not escape regulation by claiming that the salt is not listed on Appendix X for the chemicals with this footnote.

(e) All compounds with PCBs, Cobalt and Tin are covered when present in RCRA listed wastes (i.e., F, K, U and P wastes) as therefore, are considered to be part of the HWIR Exemption List.

TABLE 3.—APPENDIX X HWIR EXEMPTION LEVELS
[Example]

CASRN	Chemical Name [Alternate Names]	Unrestricted Management Exemption Levels			Landfill-Only Exemption Levels (mg/kg)
		Liquid (mg/l)	Semi-solid (mg/kg)	Solid (mg/kg)	
00–000–00	Chemical A	0.00X	0.00X	0.0X	0.0X

HWIR Risk Assessment

XV. What Is the Goal of the HWIR Risk Assessment?

The goal of the HWIR risk assessment is to identify wastes currently listed as hazardous that could be eligible for exemption from hazardous waste management requirements. The HWIR risk assessment estimates chemical-specific potential risks to human and ecological receptors living in the vicinity of industrial nonhazardous waste sites that could manage HWIR exempted wastes. We would use these risk estimates, along with other information, to identify the chemical-specific concentrations for exempted waste that would be protective of human health and the environment according to selected sets of risk protection criteria. As explained in Section XIX of the preamble, we developed four protection measure scenarios to capture the likely range of public protection measures.

We are not proposing exemption levels based on the results of the current version of the risk assessment. As explained in Section XVII, we believe that the model requires further evaluation before it can be used to generate regulatory levels. We are describing our methodology in detail, and we request comment on our risk assessment approach. We remain committed to the modeling effort, and hope that these comments will help us to revise our model and produce risk-based exemption levels. Before we would promulgate an HWIR exemption, we would first publish an HWIR proposal that would include specific exemption levels and give the public an opportunity to comment.

XVI. How Did EPA Develop the Current Version of the HWIR Risk Assessment?

A. What Is the Basic Approach of the Risk Assessment Used To Set Risk-Based Levels?

The risk assessment developed for the HWIR exemption is an integrated, multimedia, multipathway, and multireceptor risk assessment (3MRA) that evaluates impacts to human and ecological receptors. The national scale assessment evaluates risks that might occur from the long-term, multimedia

release of a chemical from HWIR exempted waste that is managed in facilities typically expected to handle exempted waste. We designed the assessment to provide flexibility in producing a distribution of risk outputs to describe the range of individual risks across the nation from potential exposures to HWIR exempt waste. The HWIR risk assessment has three principle components: (1) The assessment strategy, (2) the 3MRA model, which includes the chemical release, fate, exposure, and risk modules, and (3) the input data for the modules (for example, environmental setting, chemical, and meteorological data).

1. *Assessment Strategy.* The 3MRA strategy (U.S. EPA, 1999–b) describes the overall direction for the assessment. The assessment is a forward-calculating analysis that evaluates the multiple exposure pathway risks to human and ecological receptors. A forward-calculating analysis starts with a chemical concentration in a waste management unit, estimates the release and transport of the chemical in various environmental media, and predicts the exposure and risk that result from those concentrations. The strategy describes several different analytical levels that the assessment could follow depending on available resources and the amount and quality of available data. However, because of resource and data constraints, we did not implement the strategy to its fullest extent. The strategy describes the probabilistic approach to the assessment and explains how the results provide an estimate of risk on a national scale. A probabilistic analysis calculates risk or hazard by allowing some of the parameters to have more than one value, consequently producing a distribution of risk or hazard for each receptor. A parameter is any one of a number of inputs or variables (such as food ingestion rates and soil characteristics) required for the model that we developed to assess risk.

The assessment begins with a range of concentrations for a chemical in waste (five concentrations for HWIR) and estimates the associated hazards and risks to human and ecological receptors. By evaluating a range of waste concentrations and using a probabilistic approach to select many of the input parameters, we would be able to identify chemical-specific concentrations in waste that match our risk protection criteria (that is, our chosen level of protectiveness to human health and the environment). The risk protection criteria we selected are: cancer risk level, human health and ecological hazard quotients, population protection, and probability of site protection. The results would represent national distributions of receptor impacts near the waste management units typically expected to manage exempted waste over a 10,000 year period. For more information on the risk assessment approach, see the 3MRA background document (U.S. EPA, 1999–b).

2. *The 3MRA Model.* The 3MRA model automates the assessment strategy. The model consists of 18 media-specific pollutant fate, transport, exposure, and risk modules; six data processors to manage the information transfer within the system; and three databases that contain the data required to estimate risk.

The modeling protocol looks at the movement of a chemical in the environment from a variety of chemical and physical processes: release from a waste management unit; transport of the chemical through the environment; exposure to the chemical from multiple pathways to humans, animals, and plants; and estimates the resulting risks or hazards posed by the exposures. Modules evaluate a chemical's release from aerated tanks, landfills, land application units, surface impoundments, and waste piles; movement through the air, groundwater, soil, watersheds, rivers, lakes, and wetlands; concentration at drinking water wells, residential soils, and farms; bioaccumulation in plants and animals (both on land and in waterbodies); and exposures and risks to humans and animals through ingestion of contaminated materials such as food and soil, inhalation of air (human only), and direct contact with contaminated media (ecological only). We invite comment on the approach used in the risk assessment that integrates the direct and indirect exposure pathways leading to a receptor.

The 3MRA model application will assess risks to receptors temporally over a 10,000 year period. This will be accomplished by selecting each year from the present until 10,000 years from now, and assessing risks associated with constituent releases from a randomly selected waste unit at a randomly selected waste site location. Thus, 10,000 model runs will occur, with each model run representing a different year in the future. As discussed in Section XVI.A.3, each waste management unit is assumed to have different operational lifetimes (between 20–50 years) and different lengths of time during which constituents are assumed to be released from the unit (between 30–200 years). The model continues simulating releases until less than one percent of the initial mass is left or for the maximum time constituents are assumed to be released from the unit, whichever occurs first. The model balances chemical mass across exposure pathways, and reports a total chemical-specific concentration in waste that meets our protection criteria.

The model assesses risks to human and ecological receptors who might live within 2 kilometers of a waste management unit. At each location where there is a receptor, the model calculates the simultaneous exposures and resulting risks for that receptor, by adding the appropriate series of pathway-specific risks. Some of the modeled receptors might be exposed through several pathways, some might only be exposed through one pathway, and some might not be exposed at all to any pathway. From this information, the model generates, for each chemical across all sites, a distribution of risk for each receptor type (and also for all receptor types). This distribution of risk is also calculated for each of three radial distances (500 meters, 1000 meters and 2000 meters) from the center of the waste management units. An overview of the 3MRA Model is provided in U.S. EPA (1999–c). EPA directive #2182 (U.S. EPA, 1997-b) provides the system design development guidance.

Under this site-based approach, the chemical-specific distributions of risks or hazards would include all of the receptors living in the vicinity of industrial waste sites that are exposed through one or more exposure pathways as well as any receptors not exposed. For example, the distributions present the risk and hazard estimated for all receptors using groundwater at a site for drinking or showering. This includes receptors using groundwater from both wells located within the contaminated plume and the receptors outside of the plume. The receptors located outside of the contaminated plume have no risk or hazard through the groundwater pathway.

We have also designed the model to have the capability to estimate risk and hazard to only those receptors that are exposed to a chemical through one or more pathways. With respect to receptors using groundwater for drinking or showering, the distributions would reflect only the risk and hazard to the receptors located within the groundwater plume. The receptors using groundwater as a source of drinking or showering and located outside of the plume would not be included in the distribution of risk and hazard in this additional analysis.

The number of wells within the groundwater plume will vary

significantly by site, by chemical, and by waste management unit type. For the chemical (acrylonitrile) that we are providing results in the Risk Characterization Background Document (US EPA, 1999-as), we estimate that nationally up to about a quarter of the groundwater wells would be located inside the plumes at industrial Subtitle D landfill sites. It is possible that some chemical and waste management combinations would have no wells within the groundwater plume.

The extent of a plume depends on the concentration and mass of a chemical constituent in the waste management unit, physical and chemical properties of the waste, characteristics of the waste management unit, site hydrogeological characteristics and the site climate. Because these are variable factors, the extent of the plume for the contaminant varies. We estimated the number of wells inside a contaminant plume for a chemical constituent at a site by first estimating the extent of the plume at that site. The plume extent is characterized by approximate stream surfaces that separate the fluid emanating from the waste management unit and the ambient ground-water flow field, and the transverse dispersion normal to the stream surfaces.

For a given distance from the source (or the waste management unit), the lateral extent of the plume is defined as a cross-section normal to the flow field where the receptor well concentration has the probability of more than 99.74 percent of being greater than 0.001 of the maximum concentration at the center of the plume at that longitudinal distance from the waste management unit. We estimated the extent of the plume based on the assumption that the ground-water flow field is steady-state. The derivation of the plume's extent are described in Appendix D of the background document for the vadose zone and aquifer modules (US EPA, 1999–aa). We request comment on the estimates of wells inside and outside the plume of contamination developed to date, and our approach in calculating these estimates. We also request comment on our approach in measuring the degree of risk posed at receptor wells located within the modeled plume of contamination and at those wells located outside the plume.

3. *Input data.* The 3MRA Model requires over 700 input parameters covering a wide range of general data categories including: waste management unit characteristics; meteorological data, surface water and watershed characteristics; soil properties; aquifer properties; food chain or food web characteristics; human and ecological exposure factors; types and locations of human and ecological receptors and habitats surrounding the waste management unit; and chemical-specific properties and toxicity values. We implemented the assessment on a national scale but based the analysis on a regional, site-based approach. In this approach, site-based data are used when available as inputs to the model. When site-based data are not available, then data collected on a regional level, followed by data collected on a national level, are used for the evaluation. We collected a large amount of data to better describe and model plausible exposure scenarios from chemical-specific releases from the waste management units. Examples of the types of data collected to identify site-based characteristics include facility location and the physical and environmental characteristics of the sites and surrounding areas (for example, land use, human receptor locations, and ecological habitats). Examples of regional data we collected were meteorological data, soils characteristics, aquifer data, and types of ecological receptors. Data collected at the national level included human exposure factors, ecological exposure factors, human health toxicity values, and ecological toxicity values. We have made available what data were collected, where the data were obtained, how the data were collected and processed, and issues and uncertainties associated with the data collected for the database of the 3MRA model in the docket (U.S. EPA, 1999–d through –r).

We assessed the potential human health and ecological impacts at 201 individual nonhazardous industrial waste management sites. The sites were selected to be representative of the management sites found in EPA's *Screening Survey of Industrial Subtitle D Establishments* (U.S. EPA, December, 1987). We selected the 201 sites from a survey of approximately 2,700 facilities representing a total population of nearly 150,000 facilities across 17 industrial sectors that managed waste on-site and had one or more of four types of waste management units (landfill, waste pile, land application unit, and surface impoundment). We drew a simple random sample of 201 facilities from each of the 17 industrial sectors in the same proportion as each sector in the Subtitle D survey. For example, if the organic chemicals industry sector had three percent of the facilities in the survey, we randomly selected three percent (that is, six facilities) of the 201 facilities to be from the organic chemicals industry sector. The methodology for the selection of the 201 sites is explained in a background document (U.S. EPA, 1999–s). The 201 sites were used to collect site, regional, and national data to parameterize the model. We request comment on the selection methodology for the 201 sites to represent the national population of industrial Subtitle D facilities and whether to use sampling weights in future efforts.

We used measured, calculated, and estimated chemical-specific data to generate all relevant chemical-specific thermodynamic and kinetic data for the HWIR assessment. The lack of reliable measured thermodynamic data necessitated the use of data generated by computational methods. The SPARC (System Performs Automated Reasoning in Chemistry) model, which is a computational method based on fundamental chemical structure theory, was the primary tool for calculating the thermodynamic constants. The process of assembling kinetic constants for degradation pathways (hydrolysis, anaerobic biodegradation and aerobic biodegradation) focused on finding, evaluating, and summarizing measured data. Due to the complex nature of biodegradation processes, only a limited amount of measured kinetic constants were available for chemicals and are included in the HWIR chemical database. We grouped these kinetic data according to reaction conditions (that is, pH, temperature, and redox conditions). However, because the rate constant for metabolism is unavailable for most constituents given the general paucity of data on metabolic rate constants in fish, the metabolic rate constant was set to a default of zero until data can be developed for a larger universe of hydrophobic organic chemicals. We have provided the information on chemical properties in a database placed in the docket (U.S. EPA, 1999–ai) and we request comments on the information contained in the chemical database. We also request any additional information on the chemicals.

We have incorporated anaerobic biodegradation in the model for simulating the fate and transport of chemicals through the saturated zone. We conducted a workshop on the use of available anaerobic biodegradation rates and also invited industrial groups to provide available information. We reviewed all available information on the anaerobic biodegradation rates for organic chemicals in the saturated zone. The criteria used for the review and results of our review are presented in the background document (U.S. EPA, 1998–b). We invite comments on the inclusion of these data, our criteria for

evaluating the data, and any additional data on anaerobic biodegradation of organic chemicals.

We used several types of human health toxicity values for the purpose of describing the toxicological dose-responses for the chemicals evaluated. For human health effects, the toxicity values include: cancer slope factors (CSFs), in units of $(mg/kg/day)^{-1}$ for oral exposure to carcinogenic chemicals; reference doses (RfDs), in units of mg/kg/day, for oral exposure to noncarcinogenic chemicals; inhalation CSFs, derived from Unit Risk Factors (URFs), in units of $(mg/kg/day)^{-1}$ for inhalation exposure to carcinogenic chemicals; and reference concentrations (RfCs), in units of mg/m^3 for inhalation exposure to noncarcinogenic chemicals.

There are a number of sources available for toxicity values that attempt to determine the most sensitive health effects associated with the chemicals and express the relationship between dose and effect in quantitative terms. We established an order of preference for the sources of health toxicity values as follows (from most preferred to least preferred): (1) the Integrated Risk Information System (IRIS) online database of verified health benchmarks (U.S. EPA 1998–g); (2) the Health Effects Assessment Summary Tables (HEAST; U.S. EPA 1997–e); and (3) EPA's National Center for Environmental Assessment (NCEA) provisional values.

Although we used only these three sources for the toxicity values in the analysis, we received toxicity data submitted during the 1995 HWIR proposal for 32 chemicals that we evaluated in the 1995 HWIR proposal. These data included data that were peer-reviewed and published as well as data that were neither peer-reviewed nor published. EPA summarized and evaluated all of these comments with respect to their potential impact on the current toxicity values. A complete description of the comments and EPA's preliminary recommendations can be found in *Report on Consistency of Hazardous Waste Identification Rule (HWIR) Benchmarks With Current Agency Values and Guidelines* (U.S. EPA, 1997–e) and *Response to Comments on Hazardous Waste Identification Rule (HWIR) Benchmarks* (RTI, 1998). In addition, we developed a tiered approach for developing interim human toxicity values that includes using peer-reviewed, published toxicity data submitted to us and other toxicity data used by other Federal agencies in the development of their benchmarks. The methodology is described in *Conceptual Approach to Establishing Interim Human Health Benchmarks* (U.S. EPA, 1999–aw). We request comment on the use of toxicity data from other Federal agencies' benchmark development, our preliminary recommendations to use peer-reviewed, published data submitted in comments, and the draft methodology to develop interim benchmarks.

RfDs and RfCs are defined as ''an estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime'' (U.S. EPA, 1998–g). RfDs and RfCs are developed using a methodology that is designed to generate protective exposure estimates of indeterminate probability. CSFs are used to evaluate cancer risks for ingestion and inhalation exposures, respectively. Unlike RfDs and RfCs, CSFs do not represent ''safe'' exposure levels, rather, they are derived mathematically as the 95% upper confidence limit of the slope of the linear portion of the dose-response curve. That is, they relate levels of exposure with a probability of effect or risk.

We developed at least one ecological toxicity value for 35 chemicals. We gathered the data to develop these benchmarks from peer-reviewed literature and Agency-developed criteria (for example, Ambient Water Quality Criteria). The data sources for the ecological benchmarks developed for each of the chemicals are available in the technical background document (U.S. EPA, 1999–p).

We developed two types of toxicity values for this analysis. The first values are population-level values and are expressed as an applied dose in mg/kg-day. The ecological benchmarks are relevant to mammals, birds, amphibians, and reptiles. The second set of toxicity values are chemical stressor concentration limits (CSCL) that are expressed as media concentrations (for example, mg/L). These are community-level benchmarks and are relevant for terrestrial and aquatic plants, aquatic organisms, benthos, and soil organisms.

In identifying appropriate studies to develop ecological benchmarks, we developed a series of study selection criteria to ensure consistency in the interpretation of ecotoxicological data and to satisfy relevant data quality objectives. The study selection criteria address the desire for consistency across EPA programs, the appropriateness of the study data given the management goals and assessment endpoints for HWIR, and the quality of the study with respect to endpoint selection, dose-response information, and appropriate use of extrapolation techniques (*e.g.*, tools for statistical inference). In order of importance, the study selection criteria included the following: (1) relevance of study endpoints to population-level effects, (2) adequate data to demonstrate the dose-response relationship, (3) appropriateness of study design with respect to the exposure route (*e.g.*, gavage versus dietary exposure) and exposure duration, (4) quality of the study as determined by the use of appropriate dosing regimes, and statistical tools and (5) consistency with other EPA programs such as the Office of Water and Superfund.

With the exception of amphibian populations, the CSCLs are intended to represent de minimis levels of effect to communities of organisms. For amphibians, the extensive database on acute and subchronic aqueous exposures to developing organisms was used to derive CSCLs for surface water contact. For other receptor groups such as the soil and sediment communities, the study selection criteria included the following: (1) Acceptance of a benchmark by other EPA programs (*e.g.*, Great Lakes Water Quality Initiative), (2) consistency with EPA guidelines on study selection for aquatic toxicity data, (3) relevance of study to species presumed to be key functional elements of the community, (4) relevance of study endpoints to address community-level effects (*e.g.*, growth, survival), (5) adequacy of data to demonstrate dose-response relationship, and (6) quality of the study data with respect to the design (*e.g.*, field versus laboratory) and appropriate use of statistical tools to characterize effects (for example, confidence levels). The methodology for the development of these benchmarks is described in *Data Requirements and Confidence Indicators for Ecological Benchmarks Supporting Exit Criteria for the Hazardous Waste Identification Rule (HWIR99)* (U.S. EPA, 1999–ax).

B. How Does This Effort Compare With Past HWIR Risk Assessments?

Unlike previous HWIR risk assessment efforts (57 FR 21450 and 60 FR 66344), which considered groundwater and non-groundwater pathways separately, the HWIR99 3MRA Model evaluates simultaneous exposures across multiple media and pathways to estimate the resulting health and environmental effects. For example, instead of looking at the risks of a person drinking contaminated groundwater, breathing contaminated air, and eating contaminated food

separately, and at potentially different points in time, we estimated the risk from the simultaneous exposure from multiple pathways, where appropriate, across time.

To estimate the integrated and simultaneous exposures to receptors, we developed the 3MRA Model that balances chemical mass across pathways, and reports a total chemical-specific concentration in waste that meets our protection criteria over time. This approach is unlike the 1995 HWIR proposal, which modeled each pathway separately and assumed for each that all the mass went to that pathway. As a result, the 1995 HWIR proposal reported regulatory levels as both as total concentration (for the non-groundwater pathways) and as leach levels (for the groundwater pathways). Because we integrate the pathways in the 1999 HWIR risk assessment, the revised levels would be reported only as the total concentration of the chemical in the waste. We request comment on the revised approach to establish regulatory levels based only on the chemical-specific total concentration in the waste, rather than regulating on both total and leachate levels.

The model incorporates interacting modules that include:

- The source modules, which estimate the simultaneous chemical mass losses to the different media and maintains chemical mass balance of the releases from the waste management unit into the environment over time;
- The fate/transport modules that receive calculated releases from waste management units and distribute the mass through each of the media to determine the chemical concentrations in air, groundwater, soil and surface water across space and time;
- The food chain modules that receive the outputs from the fate and transport modules and estimate the uptake of chemicals in various plants and animals;
- The exposure modules that use the media concentrations from the fate and transport modules to determine the exposure to human and ecological receptors from inhalation (for humans only), direct contact (for ecological receptors only) and ingestion (for both receptor types); and
- The risk module that predicts the risk/hazard quotient for each receptor of concern.

The HWIR99 risk assessment uses a probabilistic approach to develop chemical-specific national distributions of risks. The ''Data Collection'' background document (U.S. EPA, 1999–d through r) discusses which parameters were probabilistically assessed and the quality of the data associated with each probabilistic distribution. We implemented the analysis focusing on evaluating inter-site variability across waste management unit and environmental setting characteristics. For the input parameters with probabilistic distributions, we randomly selected a value from the distribution corresponding to each parameter for each setting. The model generates a distribution of risk outputs that describe the range of individual risks across the nation. Additional discussion of the probabilistic approach can be found in the 3MRA document (U.S. EPA, 1999–b).

Another difference between the HWIR99 risk assessment and previous efforts is the use of an integrated and tiered approach for using site-based, regional, and national data to operate the 3MRA Model. We collected a large amount of data to better describe and model plausible exposure scenarios from chemical-specific releases from the waste management units. Examples of the types of data collected to identify site-based characteristics include facility locations; the physical and environmental characteristics of the sites and surrounding areas (for example, land use, human receptor locations, and ecological habitats). Examples of regional data we collected were: meteorological data, soils characteristics, aquifer data, and types of ecological receptors. Data collected at the national level included human exposure factors, ecological exposure factors, human health toxicity values, and ecological toxicity values.

In addition, our approach to the ecological risk assessment has evolved considerably since the 1995 proposal. Since the 1995 proposal, we have published a document titled *Guidelines for Ecological Risk Assessment* (U.S. EPA, April 1998–a) that provides a framework for conducting ecological risk assessments. A key component of these guidelines is the problem formulation phase of the assessment in which the assessor and manager discuss the goal of the risk assessment. Based on this guidance, we have better defined our objectives for the ecological risk assessment and more clearly stated our management goal and assessment endpoints. These objectives are further discussed in Section XVI.F.2 of this preamble.

C. What Peer Review Has EPA Conducted on the HWIR Risk Assessment and What Were the Results?

We are pursuing two separate levels of peer review activities to support the development of the HWIR risk assessment. The first level of peer review activity involved the *ORD/OSW Integrated Research and Development Plan for the Hazardous Waste Identification Rule* or simply the ''Research Plan'' (U.S. EPA, 1998–f). The Research Plan defines the overall risk assessment strategy. The second level of peer review activity addresses internal supporting databases and modules (for example, the chemical properties database, certain fate and transport modules). We have not completed the independent peer review of all support databases and modules and have not yet addressed all of the comments received for those modules peer reviewed. The peer review comments received to date are in the docket for today's proposed rule. When we publish a revised risk assessment for public notice, we will also give notice of any further peer review comments and how we address those comments.

Peer Review of the Research Plan. The Research Plan was prepared in part as a response to comments on the HWIR 1995 risk assessment. The plan responded to comments from the Science Advisory Board (SAB) (SAB, 1996), comments from the U.S. EPA's Office of Research and Development (ORD) and other internal EPA commenters, and the public. A joint task force between the Office of Solid Waste (OSW) and ORD was formed in order to build a ''good science'' HWIR assessment strategy and implementation technology. The Research Plan is the embodiment of six guiding principles:

1. Requiring a risk-based assessment strategy;
2. Requiring a site-based multimedia, multipathway, and multireceptor risk model;
3. Requiring the necessary assessment databases;
4. Requiring a computer-based technology;
5. Requiring a sound science foundation; and,
6. Conducting the necessary peer reviews.

We sought to particularly address comments resulting from the HWIR95 SAB review. In addition, we conducted a peer review of the Research Plan through an independent evaluation by national experts outside of EPA (Small, Cohen, and Deisler, 1998).

In general, the comments on the Research Plan were favorable. All the reviewers indicated that we had made many improvements recommended by the SAB, resulting in a product superior to that of HWIR95. The reviewers were also pleased with the layout and detail presented in the documentation. The reviewers, however, did have comments

on the current effort. One set of comments was directed at the complex nature of the multi-module system and suggested that a simpler system might be the more appropriate tool, in light of varying model sophistication and data quality. While the reviewers applauded the efforts for the establishment of parameter distributions through Monte Carlo, they expressed their concern as to its transparency to both the scientific and public communities. A complete set of peer review comments on the Research Plan is available in the docket.

As we implemented the strategy set out in the Research Plan, we found that practical limitations forced us to simplify the approach laid out in the plan. A discussion of some of those limitations is found in Section XVII of this preamble and in the technical background document (U.S. EPA, 1999-at).

Peer Review of the HWIR99 3MRA Model. The HWIR99 Model is an integrated system of databases, system processors, and modules. The three databases and six processors that were developed are new and specific to the HWIR99 rulemaking effort. The modules used are a combination of existing models (for example, ISCST3, an air dispersion model) and newly developed models. An extensive external peer review is planned to review all 27 model components (18 modules, three databases, and six processors). As with the Research Plan peer review, each model component was or will be reviewed by a group of independent experts in that respective field. These reviewers are charged with specific scientific concerns unique to each component. Because of the large number of components developed and the timing of their development, this activity has been phased over time and is on-going. Copies of the peer review charges that we have sent out and the peer review comments we have received are available in the docket.

In response to the peer review comments received so far, we have made specific technical modifications to many of the model components, and have worked to improve the transparency and clarity of the documentation. We will continue to review and address the peer review comments and comments from the public as we refine the model in preparation for the final HWIR rulemaking.

D. Which Waste Management Units Did EPA Model?

We modeled five waste management units that represent typical management scenarios that are likely disposal destinations for exempted wastes. The modeled units include landfills, waste piles, land application units, surface impoundments, and aerated tanks. For the landfill, waste pile, land application unit, and surface impoundment, we extracted data related to the location and size of each of these units from the EPA survey of industrial Subtitle D establishments in the U.S. (U.S. EPA, 1987). For the aerated tanks, we extracted size data from *Hazardous Waste TSDF—Background Information for Proposed RCRA Air Emission Standards* (U.S. EPA, 1991-b). Because we had no location data for aerated tanks, we assumed that aerated tanks could be located at any location where a surface impoundment currently exists. Each of the units is discussed below and the release pathways are summarized in Table 4.

Within each type of waste management unit, we sought to maintain mass balance. We begin with a total mass of chemical and partition the mass among volatile, liquid, and sorbed phases. Mass released via each phase is no longer available for partitioning to and release through other phases. The partitioning algorithms and media coefficients that we used are described in the two technical background documents for the modules for the sources (U.S. EPA, 1999–t and –u) and module verifications are described in U.S. EPA (1999-ad and -ae).

We are presenting an approach in the HWIR 3MRA model to address the physical relationship between waste concentrations and leachate concentrations, and mass limitations in the leachate. In the 3MRA model we start with a specified concentration of a chemical constituent and the total mass in a waste management unit, partition the constituent in the waste unit into various environmental media. The partitioning takes into consideration the physical and chemical characteristics of the chemical and the characteristics of the media. The relationship in the model, between the concentration of a chemical constituent in the waste and its concentration in the leachate, depends on these physical and chemical characteristics. The initial chemical mass in the waste management unit depletes with time due to partitioning, degradation and transport. The 3MRA model assumes the initial mass to be finite and then depletes. The concentration of a chemical constituent in a downgradient well is initially zero, gradually reaches a maximum and then declines as the mass released from the waste management unit passes the receptor well area. The details of the partitioning of the chemical mass based on the relationships between the waste and the leachate depend on the physical characteristics of the chemical constituent and the environment. For example, the relationship for organic chemicals depends on the fraction of organic carbon in the waste and other factors. For metals, the relationship depends on the pH, the presence of other inorganic and organic species, temperature, and other factors. This is further described in the various waste management units being modeled in the 3MRA model for HWIR99 (U.S. EPA, 1999–t and –u). We request comments on this approach for establishing an association between the chemical concentration in the waste, the chemical concentration in the leachate, and mass limitations in leachate.

Landfill: We designed the landfill module to simulate the gradual filling of an active landfill and the long-term releases from the active and closed landfills. The design assumes that the landfill is composed of a series of vertical cells of equal volume that are filled sequentially. We assumed that each cell requires one year to be filled. The formulation of the landfill module is based on the assumption that the contaminant mass in the landfill cells might be linearly partitioned into the aqueous, vapor, and solid phases. The partitioning coefficients are based on those reported in the literature (U.S. EPA, 1999–aq). The model simulates the active lifetime of the landfill (30 years) and continues simulating releases until less than one percent of the initial mass is left or for a total of 200 years, whichever occurs first.

We assumed the landfill had minimal controls and was constructed below grade. In particular, we assumed that the unit has no liner; the cover at closure is a soil cover that still permits volatilization and particle emissions; and the below grade design prevents runoff and erosion.

Based on the design assumptions above, we simulated the annual release of chemical mass by leaching to the unsaturated zone underneath the landfill, volatilization to the air pathway, and particle emissions to the air pathway during the active lifetime. Because we assumed the unit was designed below grade, we did not simulate releases through runoff and erosion. In addition, we simulated losses of mass through anaerobic biodegradation and hydrolysis within the landfill.

The module incorporates other assumptions intended to improve the efficiency of the model and are described in the technical background document (U.S. EPA, 1999–t). These

include the lack of lateral transport between cells, simulation of only a single cell and then aggregation of results based on the time each cell is filled, and the assumption that waste is added at a constant concentration at a constant rate.

Waste pile: We designed the waste pile module to simulate the management of wastes in a pile situated above grade, with the releases of chemicals occurring during the operating lifetime of the pile. The unit is described fully in the technical background document (U.S. EPA 1999–t). We assume that the waste pile is a set height and constant area, and that waste in the waste pile is refreshed on an annual basis. At the end of the active period, which is 30 years in this simulation, the waste pile is removed.

Based on the design assumptions, we simulated annual releases of leachate to the unsaturated zone underneath the pile, volatiles to the air, particles to the air, particles through erosion and runoff, and dissolved chemicals through runoff. In addition, we simulated losses through hydrolysis and aerobic degradation in the surface layer and hydrolysis and anaerobic degradation in the subsurface waste pile layers.

The waste pile design did not incorporate management controls. However, we assumed the waste pile was situated in a local watershed basin, such that run-on of uncontaminated soil to the management unit did not occur and soil released from the waste pile mixed with the surficial watershed runoff.

Land application unit: We designed the land application unit module to simulate the disposal of wastes in an open field for the purpose of degradation or treatment of chemicals. This module is described fully in the technical background document (U.S. EPA, 1999–t).

The model assumes that waste is applied to the surface soil periodically and then tilled into the top layer of the soil. Waste is applied during each of the 40 years of operation. We simulated releases during the active phase and up to 200 years after the land application unit is closed or when less than one percent of the total mass remains. The waste is applied on a wet weight basis and the water content of the waste is used to calculate the total infiltration to the unsaturated zone. We also assumed that the characteristics of the waste did not alter the characteristics of the native soil. Other than tilling into the soil, we did not assume management controls were present that might limit releases from the land application unit.

Based on the design assumptions, we simulated annual releases of leachate to the unsaturated zone, volatiles to the air, particulate matter to the air, particles through runoff and erosion, and dissolved chemicals in runoff. In addition, we considered chemical losses through hydrolysis and aerobic biodegradation. Also, because these waste management units are on the land surface, they are integral land areas in their respective watersheds and, consequently, are not only affected by runoff and erosion from upslope land areas, but also affect downslope land areas through runoff and erosion. Indeed, after some period of time during which runoff and erosion have occurred from a waste management unit, the downslope land areas will have been contaminated and their surface concentrations could approach (or conceivably even exceed) the residual chemical concentrations in the waste management unit at that point in time. Thus, after extensive runoff and erosion from a waste management unit, the entire downslope surface area can be considered a ''source'' and it becomes important to consider these ''extended source'' areas in the risk assessment. It is for this reason that a holistic modeling approach was taken with the waste pile and land application unit source models to incorporate them into the watershed of which they are a part.

The land application unit is fully integrated in the local watershed and is simulated as one part of the local watershed. Thus, soils from watershed areas above the land application unit might run-on to the source and mix with the surficial soils of the land application unit. Surface impoundment: We designed the surface impoundment module to simulate the disposal of liquid wastes in an earthen material pit and the releases of chemicals during the lifetime of the unit. The module is described fully in the technical background document (U.S. EPA, 1999–u). We assumed that the impoundment was a sink in the watershed. We assumed that no liner other than native soils was present, no cover was present, and that the unit was comprised of two well-mixed phases: liquid and sediment. We also simulated the changes at the bottom of the impoundment over time as settled solids fill pore space in native soils and impact chemical transport to underlying soils and groundwater. In addition, a fraction of each surface impoundment is aerated, which enhances biodegradation and increases volatilization of some chemicals. The surface impoundment is assumed to operate 50 years and then undergo clean closure (that is, all waste is removed from the unit).

Based on the design assumptions, the surface impoundment module simulates annual release of leachate to the unsaturated zone and volatile emissions to air. Because the surface impoundment is assumed to be a sink, overland runoff was not modeled. Also, the redeposition of volatiles into the unit through precipitation was not simulated. The model accounts for several biological, chemical, and physical processes including hydrolysis, volatilization, sorption as well as settlement, resuspension, growth and decay of solids, activated aerobic biodegradation in the liquid phase (that is, a higher rate based on the amount of biomass present) and hydrolysis and anaerobic biodegradation in the sediments.

The migration of contaminants from the surface impoundments to the subsurface has not been addressed rigorously in the past versions of this module. This is primarily due to lack of understanding on the processes related to bottom sediment layers in surface impoundments. We enhanced the surface impoundment module for the HWIR99 analyses by adding the formation and characterization of the bottom layers.

Aerated Tank: We designed the aerated tank module to simulate releases from aerated tanks used for the treatment of wastewaters during the operating lifetime of the aerated tank. We chose to focus on aerated tanks because such aerated tanks would have more rapid volatilization and therefore present more air risks. The module is described fully in the technical background document (U.S. EPA, 1999–u).

We selected aerated tanks from the *Hazardous Waste TSDF—Background Information for Proposed RCRA Air Emission Standards* (U.S. EPA, 1991–b) to populate the database of unit characteristics. We further limited the aerated tanks in our database by not including aerated tanks that were the size of a drum or smaller because such units are more likely to be short-term units and would also present lower risks. We also assumed that an aerated tank would operate as long as the surface impoundment and therefore selected 50 years as the operating time for an aerated tank. However, we assumed each aerated tank only had a maximum lifetime of 20 years, and therefore, the operating lifetime would include the replacement of the aerated tank every 20 years. Finally, we assumed that the aerated tanks did not

fail or leak for the purposes of the long-term exposure scenario.

Based on the design assumptions, we simulated annual volatile emissions to air. Because we did not model failures of the aerated tanks, we did not simulate leaching to the unsaturated zone or overland runoff. We did estimate losses through hydrolysis and activated aerobic biodegradation. Finally, we did not estimate redeposition of contaminants in to the aerated tank from rainfall. We request comments and suggestions on the methodologies used for modeling the environmental releases for HWIR99, and the data and methodologies used to support the overall modeling framework.

TABLE 4.—HWIR UNIT TYPES AND RELEASE MECHANISMS

	Leaching to groundwater	Volatilization	Wind-blown dust	Runoff and erosion
Landfill	X	X	X	.....
Waste Pile	X	X	X	X
Land Application Unit	X	X	X	X
Surface Impoundment	X	X	.....	.....
Aerated Tanks	.....	X	.....	.....

E. What Types of Environmental Releases Did EPA Consider When Determining How Chemicals Move Through the Environment?

We modeled four environmental media into which chemicals could enter after release from a waste management unit : (1) Atmosphere, which includes modeling of dispersion of volatiles and particles from waste management units, (2) watershed, which includes modeling the response of watersheds to runoff from waste management units, (3) surface water, which includes modeling of migration of chemicals in surface water, and (4) groundwater, which includes modeling of the migration of chemicals in the subsurface. We also modeled three food chain pathways that could contribute to a receptor's exposure. These were the farm food chain for human receptors, the terrestrial food web for the ecological receptors, and the aquatic food web for human and ecological receptors.

We have attempted to use state-of-the-science procedures to model the fate and transport of chemicals. However, because of the national scale of the assessment and the complexity of probabilistic multimedia modeling, we had to select or simplify our modules to make them computationally efficient yet maintain a strong science-based assessment. The modules described here are presented in more detail in the technical background documents that are cited. We request comments and suggestions on the methodologies used for modeling the environmental fate and transport for HWIR99, and the data and methodologies used to support the overall modeling framework. The uncertainties associated with each of the modules of 3MRA are described below, and additional uncertainties are discussed in Section XVII of this preamble.

1. Atmospheric Modeling: The HWIR99 atmospheric modeling provides an annual average estimate of air concentration of dispersed chemicals and annual deposition rate estimates for vapors and particles at various receptor points in the area of interest. The area of interest is defined by a 2 km radius measured from the edge of the largest area source at the site. The chemicals are assumed to be in the form of volatilized gases or fugitive dust emitted from area sources. The atmospheric module simulates the transport and diffusion of the chemical. The simulated air concentrations are used to estimate biological uptake from plants and human exposures due to direct inhalation. The predicted deposition rates are used to determine chemical loadings to watershed soils, farm crop areas, and surface waters. The details of the atmospheric modeling are presented in the atmospheric modeling background documents (U.S. EPA, 1999–v through –x).

The atmospheric concentration and deposition of chemicals were determined through a steady-state Gaussian plume modeling approach using the Industrial Source Complex-Short Term (ISCST3) model. This model, which was tailored to the HWIR99 risk assessment, uses hourly meteorological data and provides estimates of contaminant concentration, dry deposition (particles only) and wet deposition (particles and gases) for user-specified averaging periods (annual for HWIR99).

Our preliminary model runs indicated that it was not computationally feasible to run ISCST3 on an hourly basis for the lifetime of the unit. To reduce the computational burden, we made several simplifications to air modeling. One simplification was to use a long-term estimate of the concentration and deposition. We ran ISCST3 using normalized emissions from the units to produce annual average concentration and deposition estimates. These estimates were converted to yearly estimates by multiplying the normalized-concentration and annual deposition predictions by the emission rate for each year. Annual averages were then divided by 365.25 to provide predictions in the required daily average units.

A second simplification was to model a fraction of the hours in a year. We used the Sampled Chronological Input Model (SCIM) to sample the long term meteorological record at regular, user-specified intervals and scale the model results at the end to produce the annual average estimates. We conducted a study to determine the optimum sampling interval (U.S. EPA, 1998–c). The study showed that for dry deposition, sampling every 193rd hour from a 5-year database produced results essentially the same as those obtained when using the full meteorological record. However, this simple sampling scheme significantly underestimated wet deposition, particularly at sites with infrequent precipitation. For wet deposition, we included an additional sampling interval (every eighth hour) during hours with precipitation. This resulted in estimates that were not significantly different than those obtained from the full record.

A third simplification involved deposition of gases. Currently, there are no air models that contain algorithms specifically designed to model the dry deposition of gases. In place of algorithms, we used a transfer coefficient to model the dry deposition of gases. A concern with this approach is that deposition would be calculated outside the model, which precludes the consideration of the deposition in the amount of material depleted from the plume. This results in non-conservation of the mass in the system.

A final simplification is the use of a scavenging coefficient for all gases that is based on approximating the gases as

very small particles. This approach eliminates the need for running ISCST3 for each specific chemical, thus reducing the overall runtime. This simplification might lead to under-prediction of wet deposition for some gases and over-prediction for others depending on the Henry's Law coefficient for the gas.

2. *Watershed modeling:* The watershed module is based on conceptual and mathematical models that are very similar to those used for the land application unit and waste pile sources, that is, the combined ''local watershed/soil column'' algorithm described in Section 3.4 of U.S. EPA (1999–y). As implemented in the watershed module, the model is a dynamic, one-dimensional (vertical), fate and transport model that also includes hydrological functionality. Each watershed is independent of other watersheds and is simulated individually. Each watershed is conceptualized as a ''soil column'' with chemical loads being deposited on its surface from aerial deposition. The deposited loads are in the form of a varying annual average time series. The vertical distribution of the chemical as a function of time is then simulated by the model.

Fate and transport processes simulated by the watershed module are volatilization, leaching, runoff, erosion, infiltration and biological and/or chemical degradation. Hydrological functionality includes storm event-specific runoff estimates, based on the Soil Conservation Service's ''curve number'' method, storm event-specific soil erosion losses, based on the (modified) Universal Soil Loss Equation, and infiltration/recharge estimates based on daily runoff, evapotranspiration, and soil moisture modeling. The theoretical background and the implementation of the watershed module are presented in the background document (U.S. EPA, 1999–y).

The chemical loads to a waterbody simulated by the watershed module are indirect loads only. The sole source of chemical is aerial deposition. Chemical loads to the waterbody resulting from *direct* runoff and erosion from a waste management unit are simulated by the appropriate source module (land application unit or waste pile). Similarly, if a receptor is located in a buffer area between a waste management unit and the downslope waterbody (that is, in the ''local watershed''), the *total* surficial soil concentration that the receptor is exposed to is the aerial deposition-related concentration simulated by the watershed module *plus* the runoff/erosion-related concentration simulated by the relevant source module.

Because the surface-transport processes in the watershed module are hydrologically related, the land areas surrounding the waste management unit are disaggregated on a watershed basis, and each watershed delineated is modeled independently. A watershed can vary in size from a sheet flow-only ''hillside,'' similar to the ''local watershed'' construct of the land application unit and waste pile, to much larger areas encompassing regional stream or river networks. In all cases, a given watershed is modeled as a single, homogeneous area with respect to soil characteristics, runoff and erosion characteristics, and chemical concentrations in soil. No spatial disaggregation below the watershed level is made, that is, no spatial chemical concentration gradients are simulated across the ground surface of a given watershed.

There are a number of limitations of the watershed module that are imposed by the overall HWIR objectives and system design, for example, the practical inability to calibrate models to site-specific data. In addition, the hydrology submodels (the curve number method for runoff and the use of the Universal Soil Loss Equation) are relatively simplistic methodologies intended to yield planning-level estimates.

Another limitation is the possibility of spatial dilution of hot spots from atmospheric deposition. Because each watershed is modeled as a single, homogeneous area with an annual atmospheric loading based on the overall watershed average, any relative hot spot falling in a much larger watershed will become spatially diluted, and associated risks to humans or ecological receptors will be underestimated if those receptors spend most or all of their exposure duration within the hot spot itself.

Uncertainties of the watershed module pertain both to uncertainties in assumed functional forms of submodels (for example, first order reaction kinetic assumptions, relationship of runoff to precipitation) as well as uncertainties in parameter values. Parameter uncertainties are mitigated by the use of probabilistic sampling methods for these parameters. However, given the very limited number of realizations that are available, these parameter uncertainties are not completely quantified.

3. Groundwater modeling: The groundwater pathway consists of two components: flow and transport in the vadose zone (that is, the unsaturated zone directly below the unit), and flow and transport in the saturated zone. The modules for these two components are based on the flow and transport modules in EPA's Composite Model for Leachate Migration with Transformation Products (EPACMTP) (U.S. EPA, 1996–a and –b and 1997–c). The vadose-zone module (VZM) simulates moisture migration and transport of contaminants between the waste management unit and the water table. The saturated zone module (SZM) simulates flow and transport of contaminant in the aquifer over which the waste management unit is located, and determines contaminant concentrations at receptor wells, and mass fluxes to nearby downgradient surface water bodies. Details of the two modules are provided below.

Vadose Zone Module (VZM). Flow in the vadose zone is modeled as steady-state and one-dimensional (vertical) from underneath the source and the surficial soil outside the unit toward the water table. The lower boundary of the vadose zone is the water table. The flow in the vadose zone is predominantly gravity-driven, and therefore the vertical flow component accounts for most of the fluid flux between the source and the water table. The flow rate is determined by the long-term average infiltration rate through the waste management unit. Contaminant is transported in the vadose zone by advection and dispersion. Initially, the vadose zone is assumed to be contaminant-free and contaminants are assumed to migrate vertically downward. The technical details on the VZM are provided in the background documents for the vadose zone (U.S. EPA, 1999–aa and –ac).

The VZM receives the net rate of vertical downward percolation from the waste management unit through the unsaturated zone and to the water table. Infiltration rates and contaminant mass fluxes emanating from the unit are provided as a time series of annual average rates. The VZM require an effective steady state infiltration rate and annual average contaminant concentrations. In calculating the effective infiltration rate, the VZM conserves mass and uses the full time series of annual average rates.

The output of the VZM are a time series of contaminant concentrations, the times at which the concentrations are reported, the effective infiltration rate, and the duration of the source boundary condition.

The module includes the following limitations:

- Transient effects of the flow are not considered.

Multi-phase flow and transport are not permissible. Non-Aqueous Phase Liquid (NAPL) flow and transport are not permissible. (For more information on NAPLs please see Section XVII.D.3.)

- Vapor-phase diffusion is not allowed.
- Fingering effects in the vadose zone are excluded.
- Clay lenses or potential flow and transport barriers in the vadose zone are not considered.
- Decay is limited to first-order. Lag time for decay is not considered.
- The transport domain in the saturated zone is kept constant. Effects due to mounding caused by infiltration from waste management units are not considered. These effects would decrease the depth of the flow and transport domain in the vadose zone.

Saturated Zone Module (SZM). For HWIR 99, the SZM simulates groundwater flow using a one-dimensional steady-state solution for predicting hydraulic head and Darcy velocities. The aquifer is assumed to be of uniform thickness, subject to recharge along the top of the aquifer with a regional hydraulic gradient. The saturated zone transport module simulated the advective-dispersive transport of dissolved one dimension with the other two dimensions added analytically (pseudo three dimensional). The technical details on the SZM are provided in the background document for the saturated zone (U.S. EPA, 1999–aa, U.S. EPA, 1999–ab).

In implementing, the SZM we set the initial contaminant concentration to zero. The concentration gradient along the downstream boundary is zero, and the lower aquifer boundary is taken to be impermeable. A zero concentration condition is used for the upstream aquifer boundary. Contaminants enter the saturated zone through a patch source on the upper aquifer boundary directly beneath the source. Recharge of contaminant-free infiltration water occurs along the upper aquifer boundary outside the patch source. Transport mechanisms considered are advection, dispersion, linear or nonlinear equilibrium adsorption, and first-order decay.

The major simplifying assumptions used to simulate contaminant transport in the saturated zone are:

- The flow field is at steady state.
- The aquifer is homogeneous and initially contaminant free.
- Adsorption onto the solid phase is described by an equilibrium isotherm.
- Chemical and/or biochemical degradation of the contaminant can be described as a first-order process.
- The contaminants exist in two phases: solids and liquids. The liquid phase is considered a dilute solution of the contaminant.
- The flow field is not affected by traversing streams, nor by extraction wells.
- Mass lost to streams located between the wells and the waste management units is assumed to be small compared with the bulk of the contaminant mass in the saturated zone. All the surface waters are assumed to be gaining surface waters; in other words, groundwater is always assumed to flow from the aquifer into the stream or other surface water body. Down-gradient wells beyond the streams or surface waters are assumed to be unaffected by the presence of surface waters.

The module requires the input of an effective, steady-state recharge rate from the VZM. The primary outputs of the SZM are annual average concentrations at observation/receptor well locations for all chemicals and annual average mass fluxes to surface waters or all chemicals.

Although we did not implement this feature because of time constraints, the saturated zone module (SZM) can factor the effects of fractures in porous media into the modeling. Similarly, we also have the ability to incorporate effects of heterogeneity in aquifers (U.S. EPA–ag), but did not implement this feature due to time constraints. Both of these capabilities are discussed further in the technical background document (U.S. EPA, 1999–aa) We request comments on implementing these features in the future.

The uncertainties in the modeling results are associated with the following limitations of the SZM module.

- Transient effects of the flow, recharge, and infiltration are not considered.
- Spatially varied recharge is not considered.
- Source geometry is limited to an idealized square, with two opposite sides parallel to the flow direction.
- Multi-phase flow and transport are not modeled. Non-Aqueous Phase Liquid (NAPL) flow and transport are not modeled (For more information on NAPLs, please see Section XVII.D.3.)
- Contribution of contaminant to the saturated zone via vapor-phase diffusion above the water table is not modeled.
- Karst conditions are not modeled.
- Decay is limited to first-order. Lag time for decay is not considered.
- The presence of different hydrogeologic zones in the flow and transport domain is not considered.
- The transport domain in the saturated zone is kept constant. Effects due to significant mounding caused by infiltration from waste management units are not considered.
- Domain geometry is limited to the idealized rectangular shape. Other geometries are not considered.
- Only flow to the gaining surface waters, with axes normal to the groundwater flow direction, is modeled. Effects of streams on the flow field are not considered.
- Only receptor wells with small extraction rates are considered. Effects of extraction on the groundwater flow field are not considered.

Metals Transport. The mobility of metals in the subsurface is dependent on the geochemical properties of the soil and groundwater. To account for the metal-specific interactions with various subsurface environments, we used national distributions of key geochemical parameters. In this methodology, we used the MINTEQA2 metals speciation code to generate non-linear adsorption isotherms for each metal. We produced a set of isotherms for each metal reflecting the range of geochemical environments that is expected to be encountered at waste sites across the nation. We then used this set of isotherms to generate two subsets of isotherms for each metal: one for the vadose zone, the other for the saturated zone. Within the Generalized Soil Column Model within the source models for non-wastewater waste management units, adsorption isotherm values were approximated by treating the input adsorption isotherms for metals as a random variable in the sampling scheme. We recognize that this ignores the possible dynamic effects of aqueous phase contaminant concentration, precipitation, dissolution, adsorption/desorption, and the geochemistry of media (*e.g.*, oxidation-reduction conditions) on the value of the adsorption isotherms and the fate and transport behavior of metals in general.

There are many sources of uncertainty associated with the distribution coefficients generated by MINTEQA2. These can be categorized as: (1) Uncertainty arising from model input parameters, (2) uncertainty in database equilibrium constants, and (3) uncertainty due to application of the model. The details of methodology and data used are provided in the technical background documents on metals transport (U.S. EPA, 1991–a; 1996–a; 1998–d; 1998–e and 1999–ah).

4. *Surface Water Modeling:* Chemical mass released from a waste management unit can enter the local surface waterbody network in runoff and erosion directly from the waste

management unit, from atmospheric deposition to the water surface, in runoff and erosion from adjoining watershed subbasins, and by interception of contaminated groundwater. The chemical is then subject to transport and transformation processes occurring within the waterbody network, resulting in variable chemical concentrations in the water column and in the underlying sediments. These chemical concentrations are the basis for direct exposure to ecological receptors and indirect exposure through uptake in the aquatic food web.

The HWIR Surface Water Module takes the loadings calculated by the source, atmospheric, watershed, and groundwater modules, along with data on meteorology, hydrology, environmental conditions, and chemical reactivity, and calculates the dissolved and suspended chemical concentrations throughout the waterbody network over time. The Surface Water Module consists of the core model EXAMS II (U.S. EPA, 1982 and 1997–a) and the interface module EXAMSIO (U.S. EPA, 1999–au). EXAMS is a general surface water fate model for organic chemicals. This compartment model has been used routinely by both EPA and industry analysts for the analysis of expected pesticide concentrations in generically defined environments, such as farm ponds. It has also been used for site-specific analysis of pesticide concentrations in various waterbodies around the world. The interface module EXAMSIO was developed specifically for HWIR. It reads data from other HWIR modules and databases, and builds EXAMS input files describing the waterbody environment and chemical properties, along with the command file that specifies the chemical loading history and controls the EXAMS simulation. Control is passed to EXAMS, which conducts the simulation and produces intermediate results files. EXAMSIO then processes the intermediate files and passes the output data back to the proper HWIR databases.

The surface water module as implemented by EXAMSIO and EXAMS employs several simplifications in order to meet HWIR project requirements and constraints. The project design calls for repeated long simulations (200 to 10,000 years) executed quickly (seconds to minutes). This requirement limits the temporal resolution at which simulations can be conducted. Another important constraint is limited site-specific surface water data. This constraint limits the accuracy with which a particular site can be described. The major model simplifications made in response to these project constraints include the use of annual average hydrological and loading inputs, the use of national distributions to specify some site-specific environmental conditions, and the use of a simple solids balance with no settling and burial. For sites that experience periodic drying, a small positive flow equivalent to 5 mm/year of direct precipitation onto the waterbody surface was assumed in order to keep the model functioning.

These simplifications could lead to a degree of model error in the calculated concentrations. Using annual average loadings and flows rather than daily loadings and flows will lead to calculated annual average concentrations that are biased somewhat high, depending on the correlation between flow and loading at a particular site. This bias is somewhat mitigated for reactive and volatile chemicals where the loss rate is proportional to the concentration. The use of national distributions rather than site-specific environmental data could cause calculated concentrations to be low or high at a given location, with no known general bias. The simple solids balance will overestimate suspended solids concentrations slightly in streams and more significantly in ponds, wetlands, and lakes. Calculated total water column chemical concentrations will be high, while the dissolved chemical fraction will be low. The net result for dissolved water column chemical concentrations, which are used for fish exposure, is not expected to be biased significantly high or low.

The effect of assuming a small positive flow equivalent to 5 mm/year of direct precipitation onto the waterbody in order to prevent drying is more difficult to evaluate. This procedure conducts chemical loads downstream within a remnant aquatic reach rather than within runoff over a dry bed. While the mass balance is maintained, the chemical and solids concentrations will tend to be elevated within the remnant reach. These elevated concentrations are probably realistic for years in which evaporation exceeds all hydrologic inflows.

Organic chemical simulations account for ionization and sorption as equilibrium reactions, and volatilization, hydrolysis, biodegradation, and reduction as first-order kinetic reactions. Metals are simulated as conservative chemicals that partition to suspended and benthic solids; partition coefficients are based on a literature survey that summarizes metals partitioning behavior in surface water and sediments. Mercury is simulated as three interacting components subject to methylation, demethylation, reduction, and volatilization, as well as partitioning to suspended and benthic solids.

5. Food chain modeling: We estimated chemical concentrations in fruits and vegetables, beef and dairy products, and fish (for human receptors) and in prey and plant food items (for ecological receptors) by simulating uptake from the air, water, and/or soil and transport in these food items. This uptake and transport modeling uses empirical biotransfer factors. These factors are based on the methodologies and equations in the April 1997 internal review draft of the *Methodology for Assessing Health Risks Associated with Multiple Exposure Pathways to Combustor Emissions* (U.S. EPA, 1997–f), commonly referred to as the Indirect Exposure Methodology (IEM). The food chain methodologies and equations as implemented for HWIR99 are described in the docket (US EPA, 1999–al, 1999–am, and 1999–ap).

F. Which Receptors Did EPA Model When Assessing Exposure to the HWIR Exempt Waste?

1. *Which human receptors did EPA model?* We modeled four receptor types: residents, home gardeners, farmers (beef and dairy) and recreational fishers. Some of these receptor types overlap; a resident, gardener, or farmer could also be a recreational fisher, and the farmer could be a beef farmer, dairy farmer, or both. For each receptor type, we evaluated exposures to four age cohorts: ages 1–5; ages 6–12; ages 13–19; and older than age 19.

Some of the modeled receptors might be exposed through several pathways, some might only be exposed through one pathway, and some might not be exposed at all to any pathway. Receptor are evaluated for exposures with respect to chemicals present in ambient air (both vapors and particles), soils, groundwater, fruits and vegetables, beef and dairy products, and fish. Annual exposures are chemical and environmental setting specific and are estimated to occur for up to 10,000 years or when the chemical concentration in a particular media (for example, groundwater) decreases to less than one percent of the maximum concentration for that media.

Residents breathe contaminated air and ingest contaminated soil (as an incidental contamination of hands or foods). A subset of residents have private drinking water wells and are exposed to contaminated groundwater through both direct drinking water ingestion and inhalation through showering. Those on public water

supply are assumed to have treated water that meets all drinking water standards. We used the 1990 U.S. Census block survey data to estimate the number of residents and their ages within two kilometers of each of the 201 sites evaluated.

Home gardeners are residents who are also exposed to contaminated homegrown fruits and vegetables. We estimated the percentage of the entire population within two kilometers of the waste management unit that are home gardeners based on national data presented in EPA's *Exposure Factors Handbook (EFH)* (U.S. EPA, 1997–d).

Farmers are exposed through inhalation of ambient air, inhalation of shower air, ingestion of groundwater, ingestion of soil, and ingestion of fruits and vegetables. In addition, beef farmers are exposed through ingestion of beef and dairy farmers are exposed through ingestion of milk. We estimated the numbers and types of farms and farmers within the two-kilometer area of interest from a combination of the 1990 Census data (U.S. Bureau of the Census, 1990), Geographic Information Retrieval and Analysis System (GIRAS) land use data, and county-level census agricultural data (U.S. EPA, 1994). We averaged the 1987 and 1992 Census of agricultural data to approximate 1990 (for consistency with the population census).

Recreational fishers have the same exposures as either the resident, the home gardener or the farmer, but are also exposed through fish ingestion. The number of recreational fishers at each site was estimated from the 1990 Census data (U.S. Bureau of the Census, 1990) and state-level information from the U.S. Fish and Wildlife Service National Wildlife Survey (U.S. F&WS, 1991).

Infants are assumed to be exposed through mother's contaminated breastmilk. For infant exposure through breastmilk, the maternal exposure through all pathways was summed. The mother is assumed to be an adult (as opposed to a teenager) for the purpose of calculating maternal dose in the infant breastmilk pathway. The current methodology for infant exposure would apply only to dioxin and dioxin-like chemicals. We invite comment on this approach and whether it should be applied to other chemicals in the assessment.

For each of the receptor types, we estimated carcinogenic risks assuming a nine-year exposure duration based on average exposure during this period. Nine years is the median residence duration of the distribution for all ages as reported in the Exposure Factors Handbook (U.S. EPA, 1997–d). That is, half the population would be exposed for less than nine years and half for greater than nine years. Aging of cohorts into subsequent cohort age classes, and their differing exposures, is included. For each receptor location, human risk is estimated by aggregating exposure pathways, when appropriate. The aging of a cohort into the subsequent cohort age category(s), and the resulting differences in exposure, is included in this average calculation. For non-cancer risk calculations, exposure is assumed to vary annually; we did not use a longer averaging period. Therefore, a single high year of maximum exposure would not be ''diluted'' by a multi-year averaging period. That is, we estimated non-cancer hazard quotients based on the maximum annual average concentration. This is a conservative approach which might overestimate risks. The exposure and risk methodologies are described in the *Background Document for the Human Exposure Module for the HWIR99 3MRA Model* (U.S. EPA, 1999–aj) and *Background Document for the Human Risk Module for the HWIR99 3MRA Model* (U.S. EPA, 1999–ak), respectively.

The use of the maximum one year concentration for estimation of non-cancer hazard quotients introduces a potential bias when exposure to the constituent is associated with chronic effects from long-term exposure. The annual average concentration will tend to overestimate risk, as RfDs and RfCs for chronic effects are based on lifetime average exposure. On the other hand, use of the annual average concentration will tend to underestimate risk for developmental toxicity. In this case, annual average concentrations might mask higher short-term peak exposures resulting in an underestimation of the effective HQ (primarily for women of child-bearing age). EPA's noncancer toxicity assessment methodology, however, tends not to attach a great deal of significance to specific endpoints observed in test animals, as a general concordance of effects among species has not been demonstrated. The entire body of evidence must be evaluated in each case in order to determine whether specific effects are likely in humans.

We estimated exposures for residential receptors (residents and home gardeners) at a single location in each of the census blocks in the 2-kilometer study area, and for farmers at a single farm in each of the census block groups in the 2-kilometer study area. Recreational fisher exposures are calculated and averaged across up to three randomly selected waterbodies over the entire study area. The random selection of waterbodies is made once for recreational fishers who are residential receptors, and once for recreational fishers who are farmers. We assumed that human receptors both reside and work at the receptor location identified for them during site characterization. This assumption might overestimate or underestimate exposure to an unknown degree and bias, because it is possible that individuals might reside at the identified location within the study area, but commute to work areas outside of the study area, or could commute to more highly contaminated areas within the study area.

For each receptor type, we estimated only the incremental exposures, risks, and hazards quotients for a chemical. We did not consider background exposures from natural or other man-made sources. For cancer risks, we assumed lifetime exposure risks are in direct proportion to the fraction of a lifetime actually exposed (that is, 350 of 365 days per year (15 days away per year) for each year of the exposure duration. We did not consider additive, synergistic, or antagonistic effects among multiple chemicals. This assumption might overestimate or underestimate exposure to an unknown degree and bias. In addition, we did not consider age-specific differences in exposure responses; that is, we did not vary cancer slope factors with cohort age.

TABLE 5.— HWIR RECEPTOR TYPES AND EXPOSURE PATHWAYS

	Resident	Home gardener	Farmer	Fisher	Infants
Inhalation	X	X	X	X.	
Soil Ingestion	X	X	X	X.	
Groundwater Ingestion	X (subset)	X (subset)	X (subset)	X (subset).	
Inhalation during showering	X (subset)	X (subset)	X (subset)	X (subset).	
Fruit and vegetable ingestion		X	X	X (subset).	

TABLE 5.— HWIR RECEPTOR TYPES AND EXPOSURE PATHWAYS—Continued

	Resident	Home gardener	Farmer	Fisher	Infants
Beef and/or milk Ingestion	.....	.....	X	X (subset).	
Fish ingestion	.....	.....	.....	X.	
Breast milk ingestion	.....	.....	.....	.....	X.

2. *How were human exposures estimated?* We estimated the contaminant exposure that human receptors incur (mass of contaminant per mass of body weight) based on simulated concentrations in the various environmental media or food items, pathway-specific ingestion or inhalation rates, and receptor cohort-specific body weights. Exposure factors (for example, intake rates, residence duration) were fixed for all receptors of a given type and age at each site. With the exception of the shower inhalation exposure, the methodologies and equations used for the exposure calculations are from the *Methodology for Assessing Health Risks Associated with Multiple Exposure Pathways to Combustor Emissions* (U.S. EPA, 1997–f). The shower inhalation algorithm was adapted from McKone (McKone, 1987). All methodologies and equations as implemented for HWIR99 are fully described in the technical background document: *Human Exposure Module: Background and Implementation for the HWIR99 Multimedia, Multipathway and Multireceptor Risk Assessment (3MRA) Model* (U.S. EPA, 1999–aj).

3. *Which ecological endpoints did EPA model?* We defined several ecological assessment endpoints to evaluate, based on the management goal of protecting terrestrial and aquatic ecosystems from HWIR exempted waste. The assessment endpoints that we chose to evaluate are shown in Table 6. These endpoints represent the general trophic levels within a food web and are broad enough to characterize the functionality and trophic level interactions within most habitats. In addition, these assessment endpoints generally capture the significant biota of most habitats.

TABLE 6.—ASSESSMENT ENDPOINTS CONSIDERED FOR THE HWIR ECOLOGICAL ASSESSMENT

Ecological significance	Assessment endpoints	Example	Characteristic	Measure of effect
Upper trophic level consumers; Top recipients of bioaccumulative chemicals; Represent species with large foraging ranges; Represent species with longer life spans.	Viable mammalian wildlife populations.	Deer mouse, meadow vole, red fox.	Reproductive and developmental success.	Chronic or subchronic NOAEL(s) or LOAEL(s) for developmental and reproductive effects.
	Viable avian wildlife populations.	Red-tailed hawk, northern bobwhite.	Reproductive and developmental success.	Chronic or subchronic NOAEL(s) or LOAEL(s) for developmental and reproductive effects.
Species represent unique habitat niches (e.g., partially aquatic and terrestrial); Some species are sensitive to contaminant exposure.	Viable amphibian and reptile wildlife populations (“herps”).	Frog, newt, snake, turtle.	Reproductive and developmental success.	Chronic or subchronic NOAEL(s) or LOAEL(s) for developmental and reproductive effects.
Represents base food web in terrestrial systems; Habitat vital to decomposers and soil aerators; Proper soil community function related to nutrient cycling.	Sustainable soil community structure and function.	Nematodes, soils mites, springtails, annelids, arthropods.	Growth, survival, and reproductive success.	95% of species below no effects concentration at 50th percentile confidence interval.
Primary producers of energy in ecosystems; Act as food base for herbivores; Able to sequester some contaminants; Can act as vectors to bioaccumulation; Constitute a large fraction of the earth’s biomass.	Maintain primary terrestrial producers (plant community).	Soy beans, alfalfa, rye grass.	Growth, yield, germination.	10th percentile from LOEC data distribution.
Highly exposed receptors from constant contact with contaminated media Act as vectors to transfer contaminants to terrestrial species.	Sustainable aquatic community structure and function.	Fish (salmonids), aquatic invertebrates (daphnids).	Growth, survival, reproductive success.	Ambient water quality criteria (AWQC) for aquatic life (95% species protection).
Provide habitat for reproductive lifestages (e.g., eggs, larval forms); Habitat for key invertebrate species; Act to process nutrients and decompose organic matter.	Sustainable benthic community structure and function.	Protozoa, flat worms, ostracods.	Growth, survival, reproductive success.	10th percentile from LOEC data distribution.
Primary producers of energy in the aquatic system; Base food source in the aquatic system; Can act to sequester contaminants from the water column; Act as substrate for other organisms in the water column (e.g., periphyton).	Maintain primary aquatic producers (algal & plant community).	Algae and vascular aquatic plants.	Growth, mortality, biomass, root length.	EC_{20} for algae; lowest LOEC for aquatic plants.

Our first step for selecting ecological receptors was to identify the habitats that might exist near a site. We collected GIRAS land use maps, National Wetland Inventory maps, and National Wildlife Refuge maps to plot the types of land uses around the sample sites. We then delineated habitats within two kilometers of the waste management unit to identify the habitats around the site. We identified subclasses of terrestrial habitats, aquatic habitats, and wetlands based on the regional location of the site. A detailed description of the subclasses considered is found in the background document (US EPA, 1999–an). We then used the habitat description and regional location to identify potential receptors for each site-based habitat.

The second step in the process was to assign receptors. Based on the ecological assessment endpoints, we sought to capture the range of organisms that might reside in a specific habitat and represent the functions and trophic levels typically present in that habitat. Thus, we modeled a suite of receptors that represent various trophic levels within terrestrial, aquatic, and wetland habitats. The receptors that we evaluated included: soil communities, terrestrial plant communities, mammalian populations, and avian populations for terrestrial habitats; and sediment communities, aquatic plant communities, aquatic communities, amphibian populations, mammalian populations, and avian populations for aquatic habitats. For wetlands, we assigned groups of these aquatic and terrestrial receptors based on the type of wetland present at a site. In an effort to make the assessment site-based, we used information on the location of the site to identify the receptors that might occupy different functions or trophic levels. The list of receptors by habitat is found in the background document (U.S. EPA, 1999–an). The description of the ecological risk methodologies are described fully in the *Background Document for the Ecological Risk Module for the HWIR99 3MRA Model* (U.S. EPA, 1999–ao).

4. *How were ecological exposures estimated?* Similar to estimating human receptor exposures, we estimated ecological receptor exposures based on simulated contaminant concentrations in the various environmental media and food items, pathway-specific ingestion rates, and receptor type-specific body weights. An inhalation pathway was not considered for ecological receptors. The methodologies and equations used for exposure estimates are fully described in the technical background documents: *Ecological Exposure Module: Background and Implementation for the HWIR99 Multimedia, Multipathway and Multireceptor Risk Assessment (3MRA) Model* (U.S. EPA, 1999–an).

XVII. What Are the Results of the Current Version of the Risk Assessment?

The risk assessment is designed to produce chemical-specific distributions of cancer risks or hazards to humans and ecological receptors living in the vicinity of industrial waste sites that could manage HWIR exempted wastes throughout their operating life. For each site and waste concentration, the model can generate risks for each receptor location and then sums the number of receptors that fall within a specified risk range (bin) to get the distribution of risks for the population at each site. We can use the distribution of risks at a site to determine whether a site is protected based on the percentage of the population protected, a specified cancer risk or hazard level, and the initial concentration in waste. The model then uses these data to generate a percentile distribution based on the number sites protected at a specified risk level for each waste concentration to generate the national distribution.

These results are evaluated over a 10,000 year period of exposure. This time frame applies mainly to the groundwater pathway, since receptors are exposed to chemicals via other pathways much sooner. Evaluating peak doses over this time horizon allows the model to capture the slow movement of certain chemicals through the subsurface. Although the time frame for such travel might be long, such contamination could be a serious problem when the chemical reaches the receptor wells (see, for example, the discussion at 63 FR 42157).

Many of the commenters to the 1995 HWIR proposal felt that it would be more reasonable to use a 1,000 year time frame because of the uncertainty involved in modeling so far into the future. Land use patterns, climate, environmental, other exposure assumptions and technology would be expected to change over 10,000 years, but we cannot predict what the world will be like then.

Other commenters to the 1995 proposal felt that uncertainty surrounding the modeling effort should lead EPA to choose a time period on the order of 10,000 years to ensure that human health is protected. Particularly for chemicals that do not degrade, the issue is less which generation would bear the risk of exposure to a chemical than the magnitude of risk that would be experienced once the contamination does reach a drinking water well. A comparison of results from the 1995 modeling effort suggests, for certain chemicals, a difference in exemption concentrations of over an order of magnitude depending upon whether 1,000 or 10,000 years was chosen (60 FR 66373). Modeling for other hazardous waste identification purposes has found peak concentrations of dioxin and arsenic to occur 1,500 and 8,800 years after the assumed operating life of the disposal unit (64 FR 46492 and 64 FR 46507). There might also be some uncertainty regarding when the peak concentration occurs, and the selection of a longer time frame increases the chance that peaks are considered in the assessment. We request comment on the time period over which exposure at a receptor should be evaluated.

The risk assessment is also designed to generate results that allow risk managers the flexibility to consider the results based on several risk descriptors. The risk descriptors for the human health risk and ecological risk are discussed below.

For the human health assessment, the model calculates the aggregate risk or hazard from multiple exposure pathways that occur simultaneously at the receptor location to generate the distribution of individual risks. For carcinogenic effects, we chose seven risk bins ranging from less than 1×10^{-8} to greater than 1×10^{-4} to generate the distribution. For human health hazard quotients, we chose four hazard bins ranging from less than 0.1 to greater than 10. The model can generate results for three distance rings, including within 500 meters, within 1000 meters, and within 2000 meters. The model can also generate results for 12 exposure pathways, including total ingestion and inhalation, total ingestion, total inhalation, total groundwater ingestion and shower inhalation, air inhalation, shower inhalation, groundwater ingestion, soil ingestion, crop ingestion, beef ingestion, dairy ingestion, and fish ingestion. In addition, the model can disaggregate the results by five receptor types: all receptors, residents, gardeners, farmers, and fishers. Finally, the results can be queried by three age cohorts: all ages, children 12 and under, and adults 13 and over.

For the ecological assessment, we calculate impacts to ecological receptors using the same general methodology, but we evaluate impacts to populations or communities of ecological receptors rather than to individuals. For each site, the model generates a distribution of hazard quotients (HQ) by receptor and sorts the receptors into one of four hazard bins, ranging from less than 0.1 to greater than 10. The model uses the

receptor results to evaluate impacts to several attributes of habitats, including three habitat groups (terrestrial, aquatic, and wetland), 11 habitat types (for example, forest, lake, river), nine receptor groups (for example, mammals, aquatic biota, terrestrial plants), and five trophic levels (for example, producers, top predators). The model generates results for each of the attributes by three distance categories: within 1000 meters, between 1000 and 2000 meters, and within 2000 meters. In addition, the model also generates results for the evaluation of some combinations of these attributes, including impacts by habitat group and trophic level, and by habitat group and receptor group.

Numerical results for acrylonitrile are presented in the risk characterization technical background document as an example of the types of results the model will generate (U.S. EPA, 1999-as). At this time, we have not completed final testing of the software system. Therefore, the use and interpretation of the results must be limited. The results should be viewed as representing the capabilities of the model with respect to the types of information that the model can produce. The numbers are likely to change after additional diagnostic testing and final testing of the software system.

The software system has been designed and implemented with a strong focus on Quality Assurance and Quality Control (QA/QC). The software system is comprised of three primary components; the site-based databases, the system software, and the modules for performing the required exposure and risk assessments. The system software organizes the waste site information and prepares individual datasets that are used to simulate contaminant release, multimedia fate and transport, and human and ecological exposure and risk. The system software also manages the execution of the numerous modules that simulate specific steps in the risk assessment process (e.g., source release, surface water fate and transport, ecological risk). The software development steps that we followed (and that address QA/QC) include:

- Software system design is based on detailed and peer reviewed HWIR Assessment Methodology.
- Software system is designed using object-oriented design principles and utilizing existing EPA models (ISCST, EXAMS, EPACMTP).
- Detailed system specifications are documented and reviewed before software coding is initiated.
- Data dictionaries are developed to fully define (and constrain) each data item that is shared within the system.
- Database development is designed and executed in close coordination with software system development.
- Individual developers design and conduct first level testing of all code before assimilation into the larger software system.
- System software and component modules are assimilated into a unified system with extensive testing of information flow and related data integrity.
- Execution of an initial ''technical'' verification (i.e., tracking the actual numbers through the system) of the software system using a single combination of waste site, chemical, and waste unit type.
- Execution of limited ''production'' runs using a subset of the total number of waste site/chemical/waste unit type combinations. Production runs are oriented toward producing exemption levels.
- Execution of initial full scale production runs (i.e., using all site/chemical/waste unit type) combinations.
- Execution and documentation of final tests for individual components of the software system. (This step has been delayed due to the extended nature of the development process and overall project schedule.)
- Execution of second full scale production runs (i.e., the runs that would produce the exemptions levels).

We are providing the entire software system (with documentation) and a list of software errors that we have identified in the docket. We request comment on the system, including the specifics of any errors that are identified.

A. What Are The Major Strengths of the Risk Assessment?

The HWIR risk assessment has several major strengths. These strengths are associated with the development of the 3MRA Model and associated components, the data collection approach selected to implement the regional site-based approach, and the testing and quality assurance process followed during both the developmental and implementation phases of the assessment in order to ensure the accuracy and usefulness of the information produced.

A key strength of the risk assessment is the 3MRA Model. The model, when fully operational, will represent a state-of-the-art software system designed to implement our assessment strategy. The model is an integrated, multimedia, multiple exposure pathway, and multiple receptor risk assessment tool that evaluates impacts to human and ecological receptors. The model addresses concerns raised with earlier efforts in the following ways: implementing a probabilistic approach to develop chemical-specific national distributions of risks; maintaining mass balance partitioning within each source; incorporating fate and transport components that manage chemical loadings simultaneously from multiple environmental media; evaluating a receptor's exposure through multiple pathways simultaneously; evaluating ecological impacts at a suite of representative habitats for terrestrial, aquatic, and wetland systems; and accounting for various degradation losses, including hydrolysis, aerobic, anaerobic, and activated solids biodegradation.

In selecting the fate and transport models incorporated into the 3MRA Model, we considered which state-of-the-science models would be appropriate for this national scale assessment. For example, the air models that we considered ranged in complexity from regional-scale to simple, local-scale, box models. Currently available regional-scale models do not provide estimates at a fine enough scale for use in our assessment. On the other hand, box models tend to be sensitive to the size of the box and do not provide any spatial resolution in the estimates. The air model we ultimately selected, the Industrial Source Complex-Short Term (ISCST3) model, is a steady-state, Gaussian plume model with an area source algorithm appropriate for the types of sources included in the analysis. This model has undergone peer review and various versions have been used in a large number of our regulatory analyses. Similar decisions were made for the groundwater and surface water modules.

In addition to existing state-of-the-science media transport models, we developed new modeling approaches for the sources included in our analysis. These models were designed to address comments received from the public and the SAB on the HWIR95 source models. We believe the models provide a more accurate simulation of contaminant release to all media. For example, we incorporated the following features into our models: estimating chemical mass losses through different pathways simultaneously, which allows a true, multipathway exposure and risk estimate; maintaining mass balance; estimating chemical concentrations as a function of time and depth; including

chemical mass losses such as volatilization, leaching, biodegradation, and hydrolysis; and simulating the effects of sediment accumulation on the infiltration rate in surface impoundments is modeled.

We also developed a set of food chain models that reflect the current state-of-the-science in plant uptake and bioaccumulation of chemicals in plants and animals. Although the farm food chain and terrestrial food web are similar to those used in HWIR95, each has been updated to reflect the current thinking with regard to specific chemical classes. The aquatic food web model is also newly developed and reflects the latest thinking with regard to bioaccumulation and biomagnification of different types of chemicals in aquatic systems.

Some of the major improvements made in the area of the human exposure and risk include: GIS applications for receptor locations and characteristics; management of exposure time series including discontinuous exposures across multiple pathways; aging across cohorts based on exposure durations; and determination of critical risk time periods. These areas have improved our ability to characterize national scale risks.

We have also made improvements in our ecological assessment. The resolution of the assessment goes beyond the generic systems used in HWIR95 and now includes a suite of representative habitats for terrestrial, aquatic, and wetland systems. The habitats are intended to reflect the variability of ecological systems across the United States and provide a context for selecting appropriate receptors at each site. Each habitat is characterized by site-based data such as habitat boundaries and ''common'' species and communities associated with that habitat. Over 50 representative species of birds, mammals, amphibians, and reptiles are included. In addition, simple food webs are constructed that indicate the major trophic levels and functional groups expected in each type of habitat.

Also, although the comments from the independent expert peer reviewers of the HWIR 3MRA model have not yet been addressed, EPA has reviewed those comments and they appear to be generally supportive of the overall modeling methodology and approach. The independent expert peer reviewer comments received to date are in the docket for today's proposed rule. Both the peer review comments and the public comments will be addressed prior to a final rulemaking.

Another strength for HWIR99 is the use of an overall database that provides site-based and regional specific data for a statistically representative set of industrial sites across the U.S. By selecting a statistical sample, we can use this subset of facilities to extrapolate our results to all the industrial facilities that have the types of the waste management units we evaluated. These data provide us a more realistic, rather than hypothetical, insight with respect to location of human and ecological receptors in the vicinity of the facilities. For humans, we also have data on the number of people at various locations, their age distribution, and a variety of other characteristics. However, as noted in the preamble discussions on data uncertainties (Section XVII.B) and the surface water module (Section XVI.E.4), we recognize that we were not able to directly measure many facility/site characteristics (for example, depth to groundwater; aquifer thickness; hydraulic conductivity; location of wells; type of ecological receptors; behavioral characteristics of receptors) at each representative site to estimate risk. We addressed these limitations by using regional and national data that might underestimate or overestimate a chemical's movement through the environment and the resulting exposures and risks, with no known general bias.

We undertook a number of steps during the development and implementation phases of the model and examined supporting data to ensure the model would produce useful information. We developed the model under a documented quality assurance process beginning with an understanding of how the model must perform to meet the needs of the risk assessment, and continuing through the design of the model, its testing, and implementation. We ensured that all components of the model interacted appropriately by specifying requirements that each component had to meet, including consistency of assumptions and data transfer between components. Each component was thoroughly tested and documented by the developer. We revised program code, documentation, and design specifications to resolve issues found during testing. We had or will have each component, as well as the overall model, independently tested to ensure that the model functions as the developer intended. Finally, all of the databases and underlying data went through a quality assurance protocol to ensure that data were correctly obtained from the original source, entered in the appropriate database, and properly transferred to the 3MRA model prior to implementation.

B. What Are the Major Limitations of The Risk Assessment?

The risk assessment has inherent limitations because of the complexity associated with simulating the behavior of a chemical moving through the environment from disposal in a management unit, to exposure media, and subsequent impacts on receptors. As explained below, limitations also result from the amount, type, and quality of the data used in our assessment, the set of exposure pathways evaluated, and the types of waste management units considered. In addition, both computational and resource constraints experienced during the development and implementation of the assessment limited our effort. We did not evaluate the impacts from either one-time or intermittent disposal of a waste, or the catastrophic release of potentially exempt waste from the failure of a management unit. We were not able to directly measure facility/site characteristics (for example, unit area and volume; depth to groundwater; aquifer thickness; hydraulic conductivity; location of wells; type of ecological receptors; behavioral characteristics of receptors) at each representative site to estimate risk. Finally, we were not able to calibrate or validate our model with known data sets. We present below the major limitations related to resource constraints, risk modeling, and the data used for the modeling.

1. *What are the major limitations resulting from computational and resource constraints?*

During the implementation phase of the 3MRA Model, we were limited to running a single ''iteration'' of the model for each chemical at a waste management unit/site combination to develop the distribution of protected populations and sites over a range of five waste concentrations. This means that for parameters for which we had distributions, we selected a random value for each parameter for each setting. The combination of the selected values defined what the characteristics of the setting were for the estimation of the hazard and risk distributions. Each parameter value at the setting remained fixed during the iteration over the range of concentrations evaluated. While only a single calculation was performed at each setting, we evaluated multiple settings for each chemical. In this manner, we account for uncertainty and variability across the representative

settings of possible waste management units and sites.

Because of computational constraints (that is, the limited amount of time to run the model during the implementation phase of the risk assessment), we had to limit the duration of the chemicals release from a waste unit to a maximum of 200 years. (However, once released from the unit, the chemicals are modeled for 10,000 years or until the chemical concentration decreases to one percent of the maximum concentration in each media, whichever comes first.) This constraint affects only the landfill and land application units. The waste pile is assumed to be removed after 30 years, surface impoundments are assumed to be clean closed after 50 years (that is no further release after closure) and aerated tanks are assumed to be properly maintained to prevent any leakages from occurring during their operation.

We believe that this assumption would have little impact on the potential hazard and risk results for most chemicals that are highly mobile in environmental media and do not bioaccumulate in the food chain. For less mobile chemicals, for example most metals, we would likely underestimate the amount of the chemicals released from the unit. Based on preliminary sensitivity analyses for a less mobile chemical (arsenic), less than one-quarter of the peak mass in a landfill or land application unit is predicted to move from the unit after 1,000 years. For a land application unit, the peak surface water load was not attained even after 1,000 years, even though the surficial soil concentration in the unit begins to decrease immediately after the end of the operating life (40 years).

2. What are the major uncertainties of the risk modeling? Uncertainty analysis is very complicated when conducted on multimedia assessment modeling efforts. The issues associated with how to conduct such analyses, whether to conduct quantitative vs. qualitative uncertainty analyses, and other related issues are currently being debated within the scientific community.

Sources of uncertainty in toxicological benchmarks include one or more of the following: extrapolation from laboratory animal data to humans, variability of response within the human population, extrapolation of responses at high experimental doses under controlled conditions to low doses under highly variable environmental conditions, and adequacy of the database (number of studies available, toxic endpoints evaluated, exposure routes evaluated, sample sizes, length of study, *etc.*). Toxicological benchmarks are designed to be conservative (that is, overestimate risk) because of the uncertainties and challenges associated with condensing toxicity data into a single quantitative expression.

Another important area of uncertainty involves estimates of risks to children from carcinogenic compounds. We estimated the risk of developing cancer from the estimated lifetime average daily dose and the slope of the dose-response curve. A cancer slope factor is derived from either human or animal data and is taken as the upper bound on the slope of the dose-response curve in the low-dose region, expressed as a lifetime excess cancer risk per unit exposure. However, individuals exposed to carcinogens in the first few years of life might be at increased risk of developing cancer. We modified the exposure factors for children to account for differences between adult and child receptors (for example, body weight, exposure duration). We did not adjust the cancer slope factors to account for age-specific differences in exposure assumptions (*e.g.*, body weight). However, we recognize that significant uncertainties and unknowns exist regarding the estimation of lifetime cancer risks in children. Methodologies for estimating environmental threats to children's health are relatively new. They are currently being debated within the scientific community, and will continue to evolve. The underlying assumption in our assessment that cancer risks for children can be calculated the same as cancer risks for adults has not been peer reviewed.

Non-cancer effects in children is also an area of uncertainty. Non-cancer reference doses and reference concentrations for children are based on comparing childhood exposure, for which we have age-specific data, with adult toxicity measures, where adequate age-specific dose-response data is lacking. This mismatch results in a large amount of uncertainty in the estimation of hazard quotients for children. This would sometimes result in an overestimation of children's risk and sometimes in an underestimation. This issue is still under investigation in the scientific community and no consensus has been reached.

The use of the highest annual average concentration for estimation of non-cancer hazard quotients introduces a potential upward bias on the hazard quotient, as most non-cancer toxicity benchmarks are based on lifetime average exposure. The HWIR methodology should be considered to be conservative in this respect. An exception is when exposure to the chemical is associated with developmental effects, which can result from very short-term exposure. In this case, annual average concentrations might mask higher short-term peak exposures resulting in an underestimation of the effective HQ (primarily for women of child-bearing age). The EPA's non-cancer toxicity assessment methodology, however, tends not to attach a great deal of significance to specific endpoints observed in test animals, as a general concordance of effects among species has not been demonstrated. The entire body of evidence must be evaluated in each case in order to determine whether specific effects are likely in humans.

Another uncertainty is the impact of inter-individual variability in exposure. Exposure variables (for example, media intake rates, residence duration) are fixed for all receptors of a given type and age and are not allowed to vary. These variables do vary across waste sites. Preliminary simulations suggest that this variability might not be too large given the large variability of media concentrations nationally. However, with further regionalization and refinement of environmental fate and source characterization model inputs, inter-individual variability in exposure could become a significant factor in model output in the future.

Another important area of uncertainty is the transformation of chemicals and the changes in the species of metals that can occur either in the waste management unit or in environmental media. Once chemicals are placed in a waste management unit or released to the environment, various processes such as biodegradation and hydrolysis act to change the chemical. These changes result in what we call transformation products. Often the transformation from one chemical to another results in a less toxic chemical; however, for a few chemicals, the resultant transformation products can be more toxic. For metals, an analogous transformation takes place as the pH of the waste or media can change the state of the metal, sometimes to a less toxic form and sometimes to a more toxic form. The HWIR99 analysis does not model transformation products or changes in metal species except for mercury in surface water.

Also, because the rate constant for metabolism is unavailable for most constituents given the general paucity of data on metabolic rate constants in fish, the metabolic rate constant was set to a default zero until data can be developed for a larger universe of hydrophobic organic chemicals.

The 3MRA model does include hydrolysis, aerobic biodegradation,

anaerobic biodegradation, and activated aerobic biodegradation. Each of these processes result in lower concentrations of the parent chemical and results in the formation of daughter products. Although the 3MRA can simulate the formation and transport of daughter products, we did not implement this capability in today's risk assessment because of the technical difficulties. To evaluate daughter products, we would need to track the ratio of the amounts of daughter product to parent chemical in the waste management unit. This ratio would vary considerably depending on the age of the waste management unit. Such data are not readily available. Alternatively, we could model the parent and daughter products separately assuming the waste management unit contains only the parent chemical or daughter product and select the lower waste concentration of these two numbers.

We request comment on (1) our decision to model degradation processes, including hydrolysis, aerobic biodegradation, anaerobic biodegradation, and activated aerobic biodegradation, (2) our approach for considering the daughter products in the regulatory framework, (3) the toxicity, if any, of the daughter products that might be generated, and (4) the physical conditions under which each of these degradation processes occurs. We also request information that might be available to help us factor the ratios of parent chemical to daughter product in the modeling in order to address the issue of the toxicity of daughter products.

Although we used a regional, site-based approach for this analysis, two features related to complex terrain were not modeled. First, in modeling the dispersion and deposition of chemicals in ambient air, the surrounding terrain was assumed to be relatively flat. We made this assumption to simplify the modeling and data collection effort. The area of interest for the analysis was limited to 2 kilometers from the waste management unit. We did not think it unreasonable to assume the 2 km study area was relatively flat. Complex terrain is quite important for stack sources where emissions are coming out of elevated stacks and being widely dispersed. However, all of the units in this analysis are either in the ground or slightly elevated such as a waste pile. Generally, the plumes will be close to the ground and those living closest to the waste management unit will receive the highest air exposures. By not using complex terrain in areas that are complex, the model might slightly under or overestimate exposures from these sources. A second type of feature we did not address is complex hydrogeology such as karst or highly fractured aquifers. Some fraction of the groundwater settings in this analysis have fractured flow. In general, fractured flow in groundwater can channel the contaminant plume, thus allowing it to move faster and more concentrated than in nonfractured flow environment. This would result in higher concentrations in the groundwater.

However, this analysis is conducted using site-based receptor information. Thus, even though the groundwater plume might move faster and be more concentrated, whether this would result in higher risk to receptors depends on where the receptors are located. For example, there might be no wells in the plume. By not modeling fractured flow in this analysis, additional uncertainty is added but the magnitude of this uncertainty cannot be described at this time.

Another uncertainty in the modeling methodology involves assessing risks to receptors temporally over a 10,000 year period. There are significant uncertainties regarding how exposure and environmental assumptions will change over time, and the modeling methodology does not change these assumptions over this 10,000 year period.

In addition, the modeling methodology itself is another source of uncertainty, because models and their mathematical expressions are simplifications of reality that are used to approximate real-world conditions and processes, and their relationships. The sources of model uncertainty include relationship errors and modeling errors. Models do not include all parameters or equations necessary to express reality because of the inherent complexity of the natural environment, and the lack of sufficient data to describe the natural environment. Consequently, models are based on numerous assumptions and simplifications, and reflect an incomplete understanding of natural processes.

We selected the models used in this risk assessment based on science, policy, and professional judgment. These models were selected because they provide the information needed for this analysis and because we generally consider them to be state-of-the-science. Even though some of the models used in the risk analyses are used widely and have been accepted for numerous applications, they each retain significant sources of uncertainty. Section XVI.E of this preamble, and each of the background documents associated with the different models, discuss some examples of these uncertainties. Evaluated as a whole, the sources of model uncertainty in our analysis could result in either an overestimation or underestimation of risk.

Also, EPA did not conduct a sensitivity analysis which would identify the most sensitive parameters in the model. Sensitivity analyses and the identification of the most important parameters, such as certain source term assumptions, would allow us to better characterize the uncertainty in the risk assessment. EPA recognizes that the source term assumptions associated with each waste management unit are likely to be uncertain, because the data associated with developing these assumptions were generally limited.

In addition to the uncertainties discussed here, there are also uncertainties associated with each of the risk assessment modules, as discussed in Section XVII.E.

3. What are the limitations of the data collected to support the risk assessment? Under ideal conditions, the risk assessment would be based on actual site data using measured input data at every facility for all the site-specific variables needed, including facility location, waste management unit area, waste volume, location of drinking water wells, depth to groundwater, groundwater flow direction, meteorological conditions, number and location of receptors, land use patterns and types of ecological habitats. However, we did not consider this approach because of the time and high costs associated with its implementation. Instead, we collected only a part of the model input data at the site level. We were not able to directly measure many of the facility/site characteristics (for example; depth to groundwater; aquifer thickness; hydraulic conductivity; location of wells; type of ecological receptors; behavioral characteristics of receptors) at each representative site to estimate risk. The model inputs that did not have site-based data were characterized through regional and national databases. As a result, the data used have several limitations. Overall, the use of regional and national input data rather than site-based facility and environmental data could cause estimated concentrations to be low or high at a given location, with no known general bias. Below is an overview of some of these limitations. A more detailed discussion on the limitations of the data types used in the risk assessment are presented in U.S. EPA, 1999–a through –r.

a. Site-Based Data

We used a variety of data sources with differing ''snapshots in time'' to describe the waste management unit and the surrounding environment. We relied on the survey of RCRA Subtitle D industrial waste management units (U.S. EPA, 1987) to represent potential facilities that would manage and dispose HWIR exempted waste. Although over 10 years old, this survey represents the largest consistent set of data available on facility locations and waste management unit dimensions. A sample of 201 facilities was selected from the survey to represent the types and geographical locations of waste management units at which exempt waste could be disposed. We then used other data sources for other site-based data needs, such as the environmental conditions and the number and types of human receptors in the vicinity of these 201 facilities. For example, facility location and land use patterns were from the late 1970's to mid-1980's (U.S. EPA, 1994) and human receptor type and location data were from the 1990 Census Data. It is likely that at some of the 201 facilities there have been waste management unit additions or closures, land use pattern shifts, or demographic changes since the surveys were conducted. However, we consider using relatively current land use and population data to be preferable to developing and evaluating hypothetical exposure scenarios.

To identify wetlands in the vicinity of the 201 facilities, EPA used the 1995 National Wetlands Inventory (U.S. FWS, 1995). Complete nationwide coverage is not yet available using this data source. Therefore, we also used other data sources (U.S. EPA, 1994–a, U.S. EPA, 1994–b) to help identify wetland habitats in the vicinity of the 201 sites.

b. Regional Data

Due to limited computational times for which we had to generate risk-based concentration levels, we modeled only a fraction of the hourly meteorological data at regular intervals rather than the complete period of record for the meteorological stations (for example, 30 years). This method, the Sampled Chronological Input Model (SCIM), allowed the model to run more quickly while producing long-term averages comparable to those obtained from the full data set. Different SCIM levels were applied for dry deposition (1 hour of data selected for every 193 hours) and wet deposition (1 hour of data selected for every 8 hours).

Another parameter for which we had limited data was the hourly precipitation at the meteorological stations found in the Solar and Meteorological Surface Observation Network (SAMSON), which we used for inputs to the ISCST3 air model. We developed a method in which the amount of daily precipitation was scaled from a separate climatological data set to hourly levels.

c. National Data

The 1985 survey of RCRA Subtitle D industrial waste management units (U.S. EPA 1987) only included information on landfills, land application units, surface impoundments and waste piles. The survey contained no information on the presence or design of aerated tanks, which are the fifth type of units included in today's risk assessment. We assumed that aerated tanks were located at the same facilities that operated surface impoundments. We used specific design and operating parameters for uncovered aerated tanks developed in the *Hazardous Waste TSDF—Background Information for Proposed RCRA Air Emission Standards* (U.S. EPA, 1991–b). We assumed that the characteristics of aerated tanks managing hazardous waste would be similar to aerated tanks that will manage HWIR exempted waste.

Site-based and regional datasets are not available for many of the human exposure inputs, and in those cases we used national datasets. However, some inputs, such as food ingestion rates and exposure duration data, are available by regions of the country. We decided that national exposure data were appropriate for the national scale assessment and did not expend additional time and resources on developing these data in to regional-level distributions. Rather we relied on national-scale data available in the *Exposure Factors Handbook* (EFH) (U.S. EPA, 1997–d) for the input parameters. In developing distributions for today's assessment, we fit selected statistical models to the percentile data presented in the Exposure Factors Handbook and used goodness-of-fit techniques to select distribution types rather than collecting and using all of the raw data for each exposure parameter.

d. Uncertainty in the Chemical Database

The HWIR assessment tracks individual chemicals from specific waste streams disposed of in a waste management unit into the surrounding multimedia environment at a series of locations around the country. A variety of transport processes, including volatilization, leaching, runoff, erosion, advection, dispersion, and deposition, move chemicals from the waste management units through the multimedia environment to locations where human and ecological receptors are likely to be exposed. A set of chemical-specific data are required for the environmental simulation models that are used to calculate chemical fate and characterize the resulting exposures and risks.

Some of the chemical properties such as the ionization constants are not expected to vary among the sites. Values for these properties are entered into the HWIR database (U.S. EPA, 1999–ai) as constants, and are reported as such to the environmental models for all sites. Other chemical properties such as solubility and effective hydrolysis rate constants will vary with temperature and pH. We used regression techniques or chemical equations to provide proper values for given temperature and pH conditions. Values for the regression coefficients or chemical constants are entered into the HWIR database as constants. The values for these properties reported to the environmental models vary with the temperature and pH assumed for a particular medium at a particular site. Still other chemical properties are expected to vary among sites in response to a host of unknown or unmeasured environmental conditions. Examples include biodegradation and reduction rate constants and metals partition coefficients. These properties are entered into the HWIR database as distributions with minima, maxima, and sometimes central-tendency values. The values for these properties reported to the environmental models are random functions of the specified distributions.

The uncertainties associated with the chemical database clearly vary with chemical property. For some properties, the uncertainty is associated with the thermodynamic and kinetic constants for each specific chemical. For other properties, the total uncertainty includes not only the uncertainty in the specification of the basic constants, but also the uncertainty in the equations and classification schemes used in the application of these constants to various environmental conditions (for example, temperature, pH, and redox conditions). The uncertainty associated with the thermodynamic and kinetic constants will of course be dependent on the specific chemical and the nature of constants (measured versus calculated). The uncertainty resulting from the assumptions concerning environmental conditions results from a paucity of data describing conditions at hazardous waste sites and the requirement to conduct the HWIR assessment on a national basis.

All of the data needs cannot be satisfied with measured values because the environmental conditions within which the contaminants find themselves are simply too varied and have not been studied sufficiently to enable known values to be used. Thus, we used other means of developing the required data (for example, chemical modeling and expert judgment leading to simplifying yet environmentally protective assumptions). To generate all relevant chemical-specific data needed for the HWIR assessment, we used a combination of measured, calculated and estimated data. Although measured data were preferred, the absence or scarcity of reliable measured data required the use of data that had been generated by computational methods. The SPARC computational method, which is based on fundamental chemical structure theory, was the primary tool for calculating the thermodynamic constants in the HWIR chemical database (Karickhoff et al, 1991). Although rigorous testing for SPARC's Chemical Reactivity Models is still in progress, comparison of SPARC calculated pK_as with measured values for a large number of chemicals demonstrates the reliability of this computational approach.

The process of assembling kinetic constants for degradation pathways (that is, hydrolysis, anaerobic biodegradation, and aerobic biodegradation) focused on finding, evaluating, and summarizing measured data. Measured hydrolysis rate constants were found for most of the compounds of interest. When hydrolysis data were not available, a team of expert scientists provided rate constants based on the team's experience with similar compounds, their knowledge of the theory of these processes, and their understanding of structure-activity relationships. Due to the complex nature of biodegradation processes, only measured kinetic constants for a select group of high-volume chemicals were entered into the HWIR chemical database. These kinetic data were grouped according to reaction conditions (that is, pH, temperature, and redox conditions). Each study for a particular chemical was given equal weight despite differences in how the study was carried out. As a consequence, the uncertainty associated with the range of kinetic data in the database is expected to vary by chemical.

4. *What situations are not covered in the risk modeling?* a. Combustion. In the development of the HWIR exemption, we did not model combustion scenarios. We considered possible risk introduced into the environment from the combustion of already exempted waste and concluded that such risks were more appropriately considered under regulations promulgated or to be promulgated under the Clean Air Act.

More specifically, we recognize that the technological basis of the Maximum Achievable Control Technology (MACT) standards currently being developed under the Clean Air Act (particularly under Sections 112 and 129) will help reduce risk from air emissions at nonhazardous combustors. Because the risks associated with combustion have as much to do with combustor unit design, emissions controls and unit operation as they do with the concentration of chemicals in the feed, we did not believe it practical or even possible to develop a methodology for predicting smokestack emissions, in particular the formation of products of incomplete combustion, based solely on the chemical composition of wastes that could be combusted. This judgement is consistent with our discussion in the comparable fuels exclusion, which considered a much narrower universe of waste than the wide variety of waste being considered for exemption under HWIR (63 FR 33784).

In addition, we do not believe that there will be much incentive for HWIR exempt waste to be combusted, although a few commenters to the 1995 proposal suggested otherwise. Waste meeting HWIR exemption levels should have a low Btu value, and, therefore, such waste would not be particularly attractive for fuel use. Conceivably, a generator seeking an exemption after the point of generation could, through combustion, avoid land disposal requirements, although combustion is generally more expensive than land disposal. Also, such treatment savings presume that the exemption concentration levels would be higher than LDR levels. Under such circumstances, as discussed in Section XX of this preamble, we discuss raising these LDR standards to conform with the HWIR exemption levels. The adoption of this minimize threat approach could decrease any incentive to combust HWIR exempt waste.

Some commenters requested that we consider the exemption of hazardous waste contingent upon the combustion of these wastes in a nonhazardous waste combustor. We believe that the design of such a regulatory option would require not only the specification of concentration levels of chemicals in the feed, but also operational parameters associated with the combustor. Such requirements would either make the incoming waste approach waste that could become exempt under the generic option or make the operational design associated with the combustor approach requirements for hazardous combustors. Again, limitations in our ability to precisely model and track the transformation, creation and destruction of chemicals through the combustion process would severely limit our ability to construct such an option.

We ask for comment on our consideration of risks from combustion and alternative regulatory provisions related to the HWIR exemption. One alternative is an absolute prohibition on combustion of already exempt HWIR waste. A second alternative is a more targeted restriction based on chemical content. Some persistent, bioaccumulative and toxic chemicals such as mercury are of special concern for combustion, even at levels that might allow such waste to become exempt under HWIR. Under this second alternative, HWIR wastes containing such chemicals could not be combusted.

A third alternative would structure a prohibition on combustion similar to the one designed to prevent the combustion of metal-bearing waste within the LDR program (40 CFR 268.3(c)). Such restrictions generally require the wastes to have some appreciable organic content or heating value, unless the waste is co-generated with a waste requiring combustion or unless other Federal or State requirements necessitated the reduction of organics. Having met HWIR exemption levels for organics might reduce waste eligible for post-exemption combustion, under this alternative, to practically zero. We request comment on these alternatives, including information that might trigger a combustion prohibition, and on any other alternatives for addressing risks from the combustion of HWIR wastes.

b. Beneficial uses. We selected the landfill, waste pile, surface impoundment and land application units to model because according to an EPA industrial waste screening study, these are the most likely destinations for industrial nonhazardous waste (EPA 1987). We also modeled aerated tanks because, since the screening study was done, there has been a shift away from surface impoundment to aerated tanks for managing hazardous waste. If an aerated tank-based hazardous waste becomes exempt, it is likely that it would still be managed in that aerated tank.

However, there are many other possible management destinations besides these five units, such as using the wastes as road bed, construction fill, and cement aggregate. These practices are often collectively referred to as

beneficial use. See the background document entitled *Consideration of Beneficial Use as an HWIR Waste Management Scenario* (EPA, 1999) for a discussion of beneficial uses of industrial waste.

State programs that regulate beneficial use of industrial waste would provide some protection against risks posed by this practice. However, State regulatory programs vary greatly regarding the level of regulation for these wastes. See the background document entitled *States' Use of Waste and By-Product Materials* (ASTSWMO, 1996) for a survey of states' beneficial use programs.

Some of these beneficial uses, particularly uses that involve direct exposure to the waste, could pose a greater risk than management in the five units that we modeled. We request comment which beneficial uses are especially problematic, and whether to prohibit beneficial uses of HWIR exempted wastes.

c. Non-aqueous phase liquids (NAPLs). Fate and transport modeling embedded in the HWIR risk assessment does not account for the potential of non-aqueous phase liquids (NAPLs) to migrate to the groundwater beneath the waste units. NAPLs in the groundwater provide a source of contaminants which might move away from the original release location. Even if the migrating NAPL phase contains insufficient organic liquid to reach a receptor in the free phase, the groundwater zone will still contain a zone of laterally distributed NAPL. This zone of NAPL can exist substantially beyond the bounds of the waste unit and can act as a new source of contamination beyond the unit boundaries, effectively reducing the distance between the source and the receptors.

The NAPL will dissolve into groundwater flowing through it. This could lead to chemical concentrations in the groundwater zone that are higher than the scenarios modeled in the HWIR risk assessment. The combination of reduced distance between receptors and source and the higher initial concentrations can significantly increase chemical concentrations at receptor locations.

To augment the analysis and assumptions in the HWIR risk assessment, we developed a methodology to consider the potential for HWIR exempt waste to form free phase liquids. This methodology involved comparing the exemption levels derived for chemicals of specific concern for NAPL formation with a calculated ''saturation level'' of the chemical to see if a free phase could form. In the case of aqueous wastes, this is a simple comparison of the exemption levels to chemical specific water solubility limits. Where the exemption level exceeds the solubility limit, a separate organic liquid phase could be anticipated. The case of free phase flow from waste in a semi-solid or a solid form is somewhat more complicated. See *the Analysis of NAPL Formation Potential and Cosolvency Effect* (EPA, 1999–ar) for data, calculations and methodology for these comparisons. We request comment on how to minimize the potential for NAPL contamination of groundwater due to the formation of free-phase liquids in landfills.

The subject of co-solvency and facilitated transport is a considerably more difficult phenomenon to predict and regulate. A co-solvent is an organic chemical that is partially or completely miscible in water, and can change the properties of other chemicals, increasing their mobility. Facilitated transport is a chemical or physical process that has the potential of improving the transport of a chemical in soil or groundwater. Facilitated transport can be significant at co-solvent concentrations above a few percent. See *Analysis of NAPL Formation Potential and Cosolvency Effect* (EPA, 1999–ar) for more information. EPA is soliciting comment on how to minimize the possible impacts of co-solvency on the migration of contaminants.

d. Sludges generated from HWIR-exempted liquid wastes. In modeling the risk posed by liquid wastes, we only looked at the risks posed by the liquid itself as it is managed in an aerated tank or surface impoundment. Because of the complexity of the processes involved, we did not estimate the risk posed by the sludges that would be generated from the post-exemption management of these liquid wastes. These sludges, which would normally be regulated as hazardous due to the derived-from rule, would no longer be subject to the listing code because the parent waste had met the HWIR exemption. This would be true even when the sludges themselves did not meet the HWIR exemption levels, which might happen due to the concentrating effects of de-watering.

However, if the sludges retained a high level of metals or other regulated chemicals, they might be hazardous due to the toxicity characteristic and, therefore, would continue to be regulated under RCRA Subtitle C. We request comment on whether sludges from HWIR exempted liquids would exceed the HWIR exemption levels, and whether the toxicity characteristic is adequate to capture the risks from wastes derived from exempt liquids.

e. Surface impoundments with wastes left in place. In modeling surface impoundments, we assumed that at the time of closure, all the remaining waste in the surface impoundment is removed, and therefore no source of contamination remains (beyond the chemicals that had already left the unit). If HWIR waste were to be disposed in a surface impoundment that was closed with the waste left in place, then the risk assessment could underestimate the risk posed by such waste, especially for slow-moving chemicals. We request comment whether the assumption that surface impoundments have waste removed at the time of closure is likely to have a significant impact on the risk assessment.

XVIII. How Was the HWIR Exemption List of Chemicals Developed?

A. How Did EPA Select the Chemicals That Might Be of Concern in HWIR Waste?

We focused on those chemicals that are likely to be found in listed hazardous waste, to be toxic, and to be of concern if released to the environment. This list of chemicals was gathered from Appendices VII and VIII of 40 CFR 261, Appendix IX of 40 CFR 264, the chemicals listed in 40 CFR 261.33 (e) and (f) (the P and U listings) and the chemicals listed in 40 CFR 268.40 (LDR treatment standards).

Part 261 Appendix VII contains the chemicals that were used as the basis of listing wastes from specific and nonspecific sources (F and K listings). However, it is not meant to be a complete list of hazardous chemicals found in those wastes. Part 261 Appendix VIII is a more comprehensive list of hazardous chemicals that could be used as a basis for listing a waste [see 40 CFR 261.11(a)(3)]. Part 264 Appendix IX is the list of chemicals to be analyzed for groundwater monitoring purposes. It includes hazardous chemicals that have been found at contaminated sites under the Superfund program, and could, therefore, be of concern in mismanaged industrial wastes. 40 CFR 261.33 lists chemical products that are hazardous when discarded. 40 CFR 268.40 includes a list of chemicals with treatment requirements for each hazardous waste code.

From these sources, EPA created a ''master list'' of over 600 chemicals. This list is larger than the one developed in 1995 because of the inclusion of chemicals contained in 40 CFR 261.33 and 40 CFR 268.40, and because of chemicals added to Appendix VIII as a result of the carbamate listing (62 FR 32978).

To derive the list of chemicals that we would include in the HWIR exemption (referred to as HWIR Exemption Chemicals), a number of chemicals were deleted from the master list. Some entries were deleted because they are analyzed as a different chemical (for example, lead compounds are analyzed as lead, therefore only lead is included). Other chemicals were deleted because they represented a chemical class where a specific chemical within that class was already on the list (for example, the class of tetrachlorobenzenes is represented by 1,2,4,5 tetrachlorobenzene). Finally, some chemicals, although they might pose an immediate hazard, were thought to degrade rapidly in the environment due to hydrolysis or other processes. Other efforts within the Office of Solid Waste could enhance our ability to identify additional chemicals that do not persist in the environment and should not necessarily be evaluated for the HWIR exemption (for example, ongoing waste minimization efforts on chemical persistence have evolved from a draft list of chemicals made available in a recent **Federal Register** notice (see 63 FR 60332)).

Removing chemicals from the master list for the reasons stated above reduces the number to 442, which comprises the list of HWIR exemption chemicals. This list of chemicals is not the list of chemicals for which you would be required to test as described in Section IX.A of this preamble; however, this list represents chemicals that you would have to certify are not present in your waste. These chemicals would be listed in a new appendix to 40 CFR Part 261 that can be found in Table 2 in Section XIV. For more information on how this list was developed and on the lists of chemicals removed from consideration, see *Background Document on HWIR Exemption Chemicals*, U.S. EPA, July 1999–as.

We request comment on the chemicals considered for the HWIR exemption.

B. What Chemicals Has EPA Modeled Using the 3MRA Model?

In developing the model , we selected a limited group of chemicals to produce exemption levels. Two primary factors influenced our selection of which chemicals and how many chemicals to model in the risk assessment: (1) Adequate chemical-specific toxicity data and (2) computational limitations. Our criterion for adequate toxicity data was that each chemical had at least one human health toxicological benchmark. We relied primarily on toxicity values available on EPA's Integrated Risk Information System (IRIS) and presented in the Office of Research and Development's Health Effects Assessment Summary Tables (HEAST). In addition, we evaluated other Agency toxicity information and toxicity information submitted in comments on the HWIR 1995 proposal. (see Section XVI.A.3) The list of these chemicals with benchmarks and criteria for evaluating other information is found in *Report on the Consistency of HWIR Benchmarks with Current Agency Values and Guidelines*, (U.S. EPA, 1997–e) and *Response to Comments on Hazardous Waste Identification Rule (HWIR) Benchmarks* (RTI, 1998). We request comment on the use of these sources of toxicity data.

The second factor, computational limitations, further reduced the list to 42 chemicals which we attempted to model. These 42 chemicals are listed in Table 7 below. This number of chemicals was based on our decision to design the software system for assessing multi-media, multiple pathway, and multiple receptor risk on a PC-based platform. We chose this platform rather than more advanced computers to maximize the public dissemination of the risk assessment model and results that underlie the risk-based concentration levels. This PC-based platform limited the number of chemicals EPA was capable of evaluating for this notice due to computer processing speed and data storage limitations. To provide an example of the model outputs, the results for acrylonitrile managed in a landfill are present in a background document (U.S. EPA, 1999–as).

C. How Did EPA Choose the Initial Subset of the 42 Chemicals to Model?

To select the initial set of chemicals to evaluate, we developed criteria to select chemicals from the list of chemicals with at least one benchmark. The chemicals with benchmarks were sorted into 16 groups of similar chemical and/or physical properties. The specific properties used to establish these groups included: (1) The degree of aromaticity (the number and arrangement of benzene rings); (2) similarities in volatility (for example, low molecular weight hydrocarbons all tend to be relatively volatile); (3) the presence of halogens, such as bromine and chlorine; (4) the presence of other key elements such as oxygen, nitrogen, sulfur and/or phosphorus; (5) commonalities in the use of the chemical (for example, pesticides); (6) the presence of organic functional groups such as phenols and carbamates; and (7) similarities in ionic behavior (for example, anionic metals).

We then selected candidate chemicals from each of these 16 groups. A team of EPA scientists with collective experience in toxicology, fate and transport modeling, waste chemistry and programmatic policy then reviewed the candidates and selected 42 representative chemicals. The chemical selection process involved considerations such as: (1) The total number of chemicals within a group (for example, some groups had up to 50 chemicals within the group and therefore more candidates were examined); (2) the range of expected toxicity of the chemicals within the group (for example, benzene is considered to be more toxic than toluene); (3) whether the chemical and physical property data and analytical methods for each candidate were readily available and verifiable; (4) whether there were significant differences in chemical structures within the group; (5) the differences in degree or type of halogenation (chlorinated or brominated); (6) whether the toxicity data represented a mix of isomers; (7) whether the chemical was a common and relatively toxic degradation product; (8) whether the chemicals were significant to other EPA programs or were traditionally chosen as representatives (for example, 2,3,7,8-TCDD is typically chosen as the representative for all the isomers of halogenated dioxins and furans); and (9) the frequency or expectation of finding the chemical in many process waste streams rather than for just one listing. Further details on the chemicals groupings and the specific factors used to select each representative chemical can be found in the *Background Document on the Selection of Initial Chemicals*. U.S. EPA, October 1999–at. Based on these criteria, we selected 42 chemicals to evaluate within the HWIR risk assessment model and to develop risk-based levels (see Table 7).

TABLE 7.—INITIAL LIST OF 1999 HWIR CHEMICALS SELECTED FOR EVALUATION

Chemical name [alternate name]	CASRN	Representative class
Acetonitrile	75–05–8	organonitrogen.
Acrylonitrile	107–13–1	organonitrogen.
Aniline	62–53–3	organonitrogen.
Antimony	7440–36–0	oxoanion metal.
Arsenic	7440–38–2	oxoanion metal.
Barium	7440–39–3	cationic metal.
Benzene	71–43–2	aromatic hydrocarbon.
Benzo[a]pyrene	50–32–8	polynuclear aromatic.
Beryllium	7440–41–7	cationic metal.
Bis-(2-ethylhexyl)phthalate [Di-(2-ethylhexyl)phthalate]	117–81–7	carbon/hydrogen/oxygen.
Cadmium	7440–43–9	cationic metal.
Carbon disulfide	75–15–0	organosulfur.
Chlorobenzene	108–90–7	chlorinated aromatic.
Chloroform	67–66–3	chlorinated hydrocarbon.
Chromium	7440–47–3	oxoanion metal.
Dibenz[a,h]anthracene	53–70–3	polynuclear aromatic.
2,4-Dichlorophenoxyacetic acid	94–75–7	chlorinated pesticide.
Ethylene dibromide [1,2-Dibromoethane]	106–93–4	brominated hydrocarbon.
Hexachloro-1,3-butadiene	87–68–3	miscellaneous halogenated.
Lead	7439–92–1	cationic metal.
Mercury	7439–97–6	cationic metal.
Methoxychlor	72–43–5	chlorinated pesticide.
Methyl ethyl ketone	78–93–3	carbon/hydrogen/oxygen.
Methylene chloride [Dichloromethane]	75–09–2	chlorinated hydrocarbon.
Methyl methacrylate	80–62–6	carbon/hydrogen/oxygen.
Nickel	7440–02–0	cationic metal.
Nitrobenzene	98–95–3	organonitrogen.
Pentachlorophenol	87–86–5	chlorinated phenol.
Phenol	108–95–2	nonhalogenated phenolic.
Pyridine	110–86–1	organonitrogen.
Selenium	7782–49–2	oxoanion metal.
Silver	7440–22–4	cationic metal.
2,3,7,8-Tetrachlorodibenzo-p-dioxin	1746–01–6	dioxin/furan.
Tetrachloroethylene	127–18–4	chlorinated hydrocarbon.
Thallium	7440–28–0	oxoanion metal.
Thiram	137–26–8	carbamate group.
Toluene	108–88–3	aromatic hydrocarbon.
1,1,1-Trichloroethane	71–55–6	chlorinated hydrocarbon.
Trichloroethylene	79–01–6	chlorinated hydrocarbon.
Vanadium	7440–62–2	oxoanion metal.
Vinyl chloride	75–01–4	chlorinated hydrocarbon.
Zinc	7440–66–6	cationic metal.

All but one of the 42 chemicals have available toxicological data in developing HWIR exemption levels through the HWIR risk assessment. In the case of lead, we would not develop a human health-based number from the HWIR '99 risk assessment because lead does not have the same type of toxicological value used for the other chemicals. Instead, we would refer to levels developed for other regulatory programs within EPA, which include the Superfund program, the Safe Drinking Water Program and the Lead Hazard Control Program.

Over the past four years, we developed a ''no action'' concentration for lead in soil of 400 mg/kg for three separate programs: Superfund Site Cleanup under CERCLA (Comprehensive Environmental Response, Compensation and Liability Act), Corrective Action under RCRA and Lead Hazard Control under TSCA (Toxic Substance Control Act). This level is based on protecting children from neuro-behavioral toxicity effects from multi-media exposures of lead. Historically, we have been particularly concerned about lead poisoning in children between the age of six months and seven years, and therefore have focused on these effects for our regulations. For the soil lead guidance determination under these programs, we considered risks to children from exposure to lead in air, in soil and dust, in their diet and in their drinking water (see OSWER directives #9200.4–27P and #9355.4–12 regarding RCRA and CERCLA and *Risk Analysis to Support Standards in Lead in Paint, Dust, and Soil,* (EPA 747–R–97–006), June 3, 1998, regarding TSCA). These determinations are based on the Integrated, Exposure, Uptake and BioKinetic (IEUBK) Model and assume that the child lives amongst the contamination (that is, on-site exposure).

We also considered lead levels considered safe under the Safe Drinking Water Regulations (40 CFR 141). Although we have not set a Maximum Contaminant Level (MCL) for lead in drinking waste systems, we have required water systems to reduce the levels of lead at the tap to as close to zero as possible (see the Lead and Copper Rule (LCR) under 40 CFR 141.80). In addition to requiring water systems to optimize corrosion control, the LCR also requires that water systems that exceed 15 ug/L lead in more than 10% of the taps tested meet certain other treatment requirements where appropriate. Also, guidance from EPA's Office of Drinking Water strongly recommends that source water treatment be installed if the concentrations of lead in source water exceeds 5 ug/L.

We are considering the 400 mg/kg as an appropriate and protective human health limit to exempt waste under HWIR. This level considers multiple exposures, not just exposures from drinking contaminated water, and even for the groundwater ingestion pathway, the 400 mg/kg level is based on a default value of 4 ug/L, more stringent than both the 15 ug/L and 5 ug/L levels considered within the drinking water regulations.

Hence, we request comment on setting the exemption level for lead as the lower of two values: the 400 mg/kg level for human health risks and the modeled ecological risk results. (See Section XVI for additional discussion of ecological risk assessment performed for HWIR). We request comment on this approach for developing an exemption level for lead.

Although we intended to model all 42 chemicals listed above, we identified several errors within the system during initial production runs. These errors included exceeding solubility limits for one or more waste concentrations, failing to account for sites in the results for one or more waste concentrations, and generating the distribution of results for only the exposed population. The time required to diagnose the errors and reprogram the potential fixes to the system and modules resulted in a limited time frame for generating the results for this notice. Therefore, we included the results for acrylonitrile managed in a landfill as an example.

These results are presented in the technical background document *Risk Characterization Report for the HWIR99 Multimedia, Multipathway and Multireceptor Risk Assessment (3MRA),* U.S. EPA, July 1999-as. We plan to update the model to address system errors. In addition, we expect to place in the docket results for additional chemicals and waste management unit combinations from an updated model.

Because we have not fully tested recent revisions to the model, we are not proposing these results as HWIR exemption levels at this time. For further discussion please see Section XVII of this preamble.

D. Which Additional Chemicals Might We Model in the Future?

To help us prioritize possible future exemption level development beyond the 42 chemicals in Table 5, we first focused on chemicals reasonably expected to be present in major waste streams. For a waste stream to be eligible for this exemption, those chemicals reasonably expected to be present in the waste stream would have to have exemption levels. Developing exemption levels for these chemicals would therefore allow more waste to become eligible for an HWIR exemption. For listed waste from specific and non-specific sources (that is, F and K wastes found in 40 CFR 261.31 and 261.32), this set of chemicals would include those chemicals found in Appendix VII of 40 CFR Part 261 (hazardous chemicals for which the waste was listed) and those chemicals found in 40 CFR 268.40 (regulated hazardous constituents under the LDR program).

We also focused our prioritization efforts on waste streams most likely to take advantage of the HWIR exemptions. By analyzing data on historic cost savings and the prevalence of chemicals within both large and small waste streams, we identified an additional 29 chemicals that with exemption levels could greatly increase the number of RCRA waste codes, facilities and volumes of waste eligible for the HWIR exemption. (The identification of these 29 chemicals is discussed further in *Background Document on Additional HWIR Chemicals,* U.S. EPA, October 1999–au). These chemicals are listed in Table 8.

TABLE 8.—CANDIDATES FOR ADDITIONAL HWIR EXEMPTION LEVEL DEVELOPMENT

	CAS No.	Chemical name
1	67–64–1	Acetone [2–Propanone]
2	98–86–2	Acetophenone
3	79–06–1	Acrylamide
4	79–10–7	Acrylic Acid
5	56–23–5	Carbon tetrachloride
6	7440–50–8	Copper
7	108–94–1	Cyclohexanone
8	95–50–1	Dichlorobenzene [ortho-Dichlorobenzene], 1,2-
9	107–06–2	Dichloroethane [Ethylene dichloride], 1,2-
10	110–80–5	Ethoxyethanol [Ethylene glycol monoethyl ether][Cellosolve], 2-
11	141–78–6	Ethyl acetate
12	100–41–4	Ethylbenzene
13	60–29–7	Ethyl ether [Ethane, 1,1′-oxybis]
14	64–18–6	Formic Acid
15	118–74–1	Hexachlorobenzene
16	67–72–1	Hexachloroethane
17	78–83–1	Isobutyl alcohol [2-methyl-1-propanol] [isobutanol]
18	108–39–4	meta-Cresol [3-Methyl phenol]
19	67–56–1	Methanol [Methyl alcohol]
20	108–10–1	Methyl isobutyl ketone [Hexone][4-Methyl-2-pentanone]
21	71–36–3	n-Butyl alcohol [n-Butanol]
22	79–46–9	Nitropropane, 2-
23	95–48–7	ortho-Cresol [2-Methyl phenol]
24	106–44–5	para-Cresol [4-Methyl phenol]
25	109–99–9	Tetrahydrofuran
26	76–13–1	Trichloro-1,2,2-trifluoroethane [Freon 113], 1,1,2-
27	79–00–5	Trichloroethane [Vinyl trichloride], 1,1,2-
28	75–69–4	Trichlorofluoromethane [Trichloromonofluoromethane][CFC-11]
29	1330–20–7	Xylenes, mixed isomers (ortho-, meta-, para-) [Xylenes, total]

Just as there are good candidates for additional exemption levels, there are other chemicals that are less attractive for exemption level development. The following types of chemicals might be of lower priority simply because they are

not found in most process wastes generated today. These chemicals include: (1) Chemicals no longer produced in the United States; (2) chemicals produced infrequently or in small quantities; (3) chemicals used exclusively as pesticides or herbicides; and (4) chemicals found exclusively within discarded chemical products (that is, many of the RCRA P and U listed wastes found in 40 CFR 261.33). Consistent with this prioritization, we do not believe that we need to develop exemption levels for all chemicals listed in Section XIV, to make the HWIR exemption available to a broad segment of the waste universe.

These lower priority chemicals are unlikely to be prevalent in newly generated wastes, although they can appear in site clean-up wastes or contaminated media (for example, contaminated soil). While clean-up wastes and contaminated media may become exempt under HWIR by meeting the stated requirements, the main focus of today's rule is process wastes. Other regulatory mechanisms exist within the RCRA and CERCLA programs to direct the appropriate management of these wastes.

Another consideration for the development of exemption levels for chemicals is whether we have sufficient toxicological data and they do not present any other technical issues. Many chemicals, because of a lack of human health benchmarks or other technical difficulties, are problematic for developing exemption levels. Such technical difficulties include analytical challenges in measuring chemical concentrations in waste matrices or difficulties representing the behavior of the chemical through our modeling framework.

One such chemical with toxicological information, but which presents other technical difficulties is cyanide. Cyanide has traditionally been of particular interest because of its high prevalence in hazardous waste streams. We have not pursued the development of cyanide numbers for generic waste streams using the HWIR risk assessment model because of technical concerns that include: (1) The presence of cyanide in various forms, which change with waste matrix pH, the presence of metals and cyanide concentration; (2) the complex chemistry of cyanide, both in the waste and in its environmental transport; and, (3) cyanide degradation, such as its oxidation to carbon dioxide, nitrogen and water. Further, the chemical analysis of cyanide is complicated by significant interferences and the reporting of various cyanide forms, including total, free and weak acid dissociable forms. We ask for comment on which wastes would be impacted by the absence of an HWIR exemption level for cyanide, and for comments on how to set HWIR exemption levels for cyanide, given its complex chemistry.

We also request comment on which particular chemicals and waste streams are especially suited to an HWIR exemption. We believe that direct input from waste generators specifically identifying candidate waste streams would be the most useful and targeted means of selecting additional chemicals for exemption level development.

XIX. How Would EPA Use the Results of the Risk Assessment To Set HWIR Exemption Levels?

As discussed in Section XVII, we have identified an inconsistency in the model results, which we believe demonstrates that the model is not performing as designed. In addition, we have not completed final testing of the software system. Therefore, we are not proposing HWIR exemption levels based on these modeling results. This section explains the methodology we would use to set HWIR exemption levels when the final modeling results are available. Before we would promulgate an HWIR exemption, we would first publish an HWIR proposal that would include specific exemption levels and give the public an opportunity to comment. We request comment on this methodology for generating HWIR exemption levels from the risk assessment results.

A. What Risk Protection Criteria Would EPA Use To Generate HWIR Exemption Levels?

The HWIR exemption levels would be generated based on five different types of risk protection criteria: (1) Cancer risk level, (2) human health hazard quotient (HQ), (3) ecological hazard quotient, (4) population percentile, and (5) probability of protection. By setting a value for each of these criteria, we would identify the chemical-specific waste concentrations that would be protective at those values. Each risk criterion is explained in more detail below and summarized in Table 9. For each of the risk protection criteria, we would select specific levels from a range of values for each protection criterion from which we developed HWIR exemption levels. We invite comment on which values we should select for each of the risk protection measures.

1. *Cancer Risk level.* The cancer risk level refers to a person's increased chance of developing cancer over a lifetime due to potential exposure to a specific chemical. A risk of 1×10^{-6} translates as an increased chance of one in a million of developing cancer during a lifetime. EPA generally sets regulations at risk levels between 10^{-6} and 10^{-4} (in other words, from one in a million to one in ten thousand increased chance of developing cancer during a lifetime). In the RCRA hazardous waste listing program, a 10^{-6} risk is usually the presumptive ''no list'' level, while 10^{-5} is often (used to determine which wastes are considered initial candidates for listing (see, for example, the petroleum listing at 63 FR 42117). For HWIR, we would evaluate the exemption levels that result from both the 10^{-6} and the 10^{-5} risk levels.

We do not intend to evaluate a risk higher than 10^{-5} for an HWIR exemption, because using higher levels would mean that waste could exit the RCRA hazardous waste regulatory system at a higher risk than it typically enters the system. In the 1995 HWIR proposal, we did consider using higher risk levels for our modeling under the State-based contingent management approaches, but this was contingent on having in place a State nonhazardous waste program approved by EPA, which would reduce the overall risk to 10^{-6} or 10^{-5}. Given that the HWIR exemption discussed today is designed to be self-implementing, with no direct governmental oversight of the exemption claims and no EPA review of State nonhazardous waste programs, we believe that using a cancer risk level of 10^{-4} or higher would be inappropriate.

2. *Hazard Quotient (HQ).* The HQ refers to the likelihood that exposure to a specific chemical would result in a non-cancer health problem (for example, neurological effects). The hazard quotient is developed by dividing the estimated exposure to a chemical by the reference dose (RfD) for oral ingestion pathways or reference concentration (RfC) for inhalation pathways. The RfD and RfC are estimates of the highest dose or concentration that might be considered safe. An HQ of one or lower indicates that the given exposure is unlikely to result in adverse health effects. Some programs, such as the drinking water program, set the HQ target at less than one to provide a safety factor against exposure to a chemical from other sources. For example, the drinking water program has used 20% of the RfD in setting drinking water standards (see, for example, 57 FR 31776). Within the Office of Solid Waste, we have used 25% of the RfD in setting standards for Boilers and Industrial Furnaces (BIFs) (56 FR 7134). For HWIR, we would evaluate the exemption levels that result

from both an HQ of 0.1 and an HQ of one.

3. *Ecological hazard quotient.* The ecological hazard quotient is analogous to the human health HQ, except that the estimated exposure is compared with an ecological toxicity value rather than the human health RfD or RfC. For this analysis, we developed two types of toxicity values: (1) an ecological benchmark that is analogous to the human health HQ using a RfD; and (2) chemical stressor concentration limit (CSCL) that is analogous to the human health HQ using an RfC. The ecological hazard quotient protects ecological health at the population or community level, and therefore focuses on reproductive and developmental effects, rather than the mortality of individual organisms. In developing ecological toxicity values for this risk assessment, we used the geometric mean between a No Observed Effects Level (NOEL) and a Lowest Observed Effects Level (LOEL). (Human health reference doses are based on NOELs.) This approach is similar to the approach used for developing Ambient Water Quality Criteria, where the assumption is that most, but not all, of the aquatic species and animals are protected (U.S. EPA, 1985). For HWIR, we would evaluate the exemption levels that result from both an ecological hazard quotient of one and ten.

4. *Population percentile.* The population percentile is the percentage of the population protected at the specified risk levels and hazard quotients for a single environmental setting. A setting is a specific unit at a specific site, and is defined by combining site-based information (such as unit size, and unit placement) with variable environmental information (such as rainfall and exposure rates) generated from regional and national data. For HWIR, we would evaluate the exemption levels that result from population protection percentiles of 99% and 95%.

Although the risk percentiles are meant to represent the proportion of the population protected (or, conversely, at risk), the data used to define population variability and to interpret the 99th individual risk percentile may be both quantitatively and qualitatively limited. First, there might not be a sufficient number of observations for a given input for adequately defining an upper percentile (for example, the 99th percentile) within the range of observations, which introduces uncertainty when extrapolating in the tails. Second, efforts to describe the variability are often confounded by uncertainties introduced as a bias. The bias may over-or underestimate the results to an unknown degree.

5. *Probability of protection.* The probability of protection is defined as the percentage of settings that meet the population percentile criteria. These distributions reflect the uncertainty and the variability of the model and underlying data required by the model. We generally describe a probability of protection as ''high end'' when it focuses on individual risk to those people at the upper end of the distribution, generally above the 90th percentile (%). For HWIR, we would evaluate the exemption levels that result from both 95% and 90% probabilities of protection.

By evaluating different values for each risk protection criteria, we would generate potential HWIR exemption levels for four different risk protection groups (See Table 9) . The risk protection groups are two-dimensional in nature. For example, with respect to the Group 2 criteria the interpretations for cancer and non-cancer risks are respectively:

—99% of the population are subject to cancer risks of less than 10^{-6} across 90% of the environmental settings;

—99% of the population experience exposure levels below an HQ of 1 across 90% of the environmental settings.

The combinations in Table 9 capture a range of protection levels, from most conservative (Group 1) to least conservative (Group 4). These groups are not an exhaustive look at all possible combinations of potential risk protection criteria; we could choose a different combination altogether. These groups were chosen to help bound the possible values. We request comment on which risk protection criteria to use, and in which combination.

TABLE 9.—RISK PROTECTION COMBINATIONS EVALUATED FOR HWIR RISK ASSESSMENT

	Group 1 (most conservative)	Group 2	Group 3	Group 4 (least conservative)
Risk Level	10^{-6}	10^{-6}	10^{-5}	10^{-5}
Human Health HQ	0.1	1	1	1
Eco HQ	1	1	1	10
Population Percentile	99	99	99	95
Probability of Protection	95	90	90	90

B. How Would EPA Aggregate the Human Health and Ecological Risk Information?

The risk assessment produces separate results for the protection of human receptors and the protection of ecological receptors. We would select the lower (more conservative) of these values. Thus, the resulting number would be protective of both sets of receptors.

C. How Would EPA Aggregate the Chemical Concentrations at Each Waste Management Unit Into HWIR Exemption Levels?

The risk assessment produces separate results for each of the five waste management units being modeled (surface impoundment, aerated tank, land application unit, waste pile, and landfill). To apply these results to real-world practices under the generic HWIR exemption, we defined the categories of wastes that would most likely match the scenarios we modeled.

To match the HWIR exempted wastes to their likely destinations, we would tailor the HWIR exemption levels to three broad waste form categories: (1) Liquids; (2) semi-solids; and (3) solids. These categories are identified by a waste's total suspended solids (TSS) content, which is defined as the particles that can be removed from a solution by filtration. Liquids are wastes that have less than 1% TSS by weight; semi-solids are wastes with a TSS content between 1 and 30%; and solids are waste with a TSS content greater than 30%.

We chose the 1% and 30% thresholds by examining available data on wastewater treatment and sludge processing and by considering water saturation for a ''typical'' waste passing

the paint filter test. More detailed discussion of these data sources can be found in the background document entitled *Correlation between Liquid, Sludge, and Solid Waste Forms and Surface Impoundment, Land Application Unit, and Landfill Disposal Options* (U.S. EPA, 1999-a).

We would group the unit-specific results to construct HWIR exemption levels for each waste category as follows:

TABLE 10.—HWIR EXEMPTION LEVEL CATEGORIES

	Liquids (TSS < 1%) (mg/l)	Semi-Solids (1%≤TSS≤30%) (mg/kg)	Solids (TSS > 30%) (mg/kg)
Surface Impoundment	Evaluate	Evaluate.	
Aerated Tank	Evaluate	Evaluate.	
Land Application Unit		Evaluate.	
Waste Pile			Evaluate.
Landfill			Evaluate.

As Table 10 suggests, HWIR exemption levels for liquids would be derived from releases evaluated at surface impoundments and aerated tanks. Exemption levels for semi-solids would be based on releases evaluated at surface impoundments, aerated tanks and land application units. Solids use risk-based numbers would be based on the releases evaluated at waste piles and landfills.

The exemption levels for each waste form would be determined for each waste management unit by selecting the lowest (most stringent) chemical concentration from the units evaluated. For example, the liquid exemption level would be based on the lower of the surface impoundment and aerated tank results. In developing the semi-solid numbers, we would convert the surface impoundment and aerated tank results, which are in mg/l, to mg/kg based on an assumed density of one kg/l (the density of water).

These categories of waste forms group wastes that are expected to be managed in similar ways. Some waste forms will not realistically be managed in certain management units. For example, it is unlikely that a true solid would be managed in an aerated tank system, or that a true liquid would be managed in a landfill. The liquid and solid definitions distinguish wastes that are clearly and intuitively liquid and clearly and intuitively solid from the rest of the waste universe. Creating separate exemption levels for these two waste forms should not affect the protectiveness of the exemption, and might allow for more appropriate exemption levels and greater regulatory relief.

The semi-solid category, on the other hand, represents a broad and varied universe of waste. Wastes between 1% and 30% TSS could in theory be managed in any of the five waste management units, although the more liquid wastes (for example, 1%–10% TSS) would be less likely to go to landfills and waste piles and the more solid wastes (for example, 20–30% TSS) would be less likely to go to surface impoundments or aerated tanks. Wastes going to land application units, however, could contain anywhere from 1% to 30% TSS.

We considered assigning to the category of semi-solids the lowest concentration of the results from any of the five waste management units. This approach would ensure that the concentration would be protective no matter which of the units is the ultimate destination. However, after additional consideration, we decided that the risk levels derived from the landfill and waste piles were not directly comparable to the other units. Risk values for surface impoundments, aerated tanks and land application units are derived on a wet basis (that is, they consider the volumes of water contained in the waste form), whereas the levels derived for landfill and waste piles are derived on a dry basis.

Our approach groups the risk results from surface impoundments, aerated tanks and land application units to produce the semi-solid exemption levels. To the extent that semi-solids could be disposed in a landfill or waste pile, then this formulation does not explicitly evaluate such risk. However, for many chemicals, particularly organics, risks from a land application unit would be expected to be generally greater than risks from a landfill or a waste pile, although such a judgement would be case specific. Applying the land application unit results to wastes that contain up to 30% TSS should therefore be more protective than lowering the 30% TSS threshold and applying the landfill or waste pile results.

In the 1995 HWIR proposal, we pursued a different characterization of waste form categories (see 60 FR 66388). In 1995, we distinguished between ''wastewaters'' and ''nonwastewaters'' and offered three alternatives to define the two categories. These three alternatives were based on the LDR definition of wastewaters, a 15% solids threshold, and a distinction for free liquids made on the basis of the paint filter test.

Commenters on the 1995 proposal were split in their support of these three options for defining wastewaters and nonwastewaters. Many commenters supported a distinction at 15% solids, because this threshold would, among the three proposed, best identify the way in which waste is actually managed and the way in which the results from the risk analysis were used in developing the 1995 HWIR exemption levels. Equally strong were opinions advocating consistency with the LDR definition. Commenters were concerned about multiple definitions of waste forms within the RCRA program and the complexity and confusion such differences would cause. We believe that the creation of three waste form categories will produce categories with appropriate and corresponding exemption levels, while at the same time maintaining general consistency with the LDR definitions.

A few commenters suggested the creation of three waste form categories at 1% and 15%, labeling waste less than 1% as wastewaters, wastes greater than 15% as non-wastewaters, and allowing the generator to classify wastes between these thresholds based on how they are actually managed. In today's notice, we have adopted this notion of three waste categories; however, as explained earlier we have increased the upper threshold to 30% in order to protect against risks of land applying wastes with 15–30% solids.

The concept of ''solids'' based on the 30% threshold is intended to conform with the historic consideration of wastes that do not have free liquids as defined under 40 CFR 260.10. Conceptually, these wastes would also pass the paint filter test developed to determine the presence of free liquids in either

containerized or bulk wastes (see 50 FR 18370) that established the paint filter test as well as a subsequent **Federal Register** notice (57 FR 54454) that retained the paint filter test over a proposed liquid release test. Therefore, as an alternative to the threshold of 30% TSS, we request comment on the use of the paint filter test to distinguish solids without free liquids from other solids for the purpose of the HWIR exemption.

We also do not believe it appropriate in the generic option to allow you to choose which of the three exemption levels (liquid, semi-solid, or solid) should apply to your wastes. Because there are no constraints or requirements that waste exempted under the generic option be disposed in a particular unit, there would be no way to verify that the waste ended up in the destination for which exemption levels were evaluated under the risk assessment.

As discussed in Section X.C. of this preamble, waste becoming exempt after the point of generation must comply with LDR requirements. The relationship of the waste categories for HWIR and LDR is therefore especially important. We believe that although the HWIR definition of liquids is different from the LDR definition of wastewater, these definitions are appropriate to their respective programs.(See discussion of LDR requirements for HWIR exempted waste in Section X of this preamble.)

We sought to conform the HWIR definition of liquids with the 1% threshold for TSS found in the LDR definition of wastewaters (see 40 CFR 268.2(f)). The overlap is especially useful when making any comparisons of HWIR and LDR concentration levels (for example, for the purposes of meeting treatment standards established to minimize threats to human health and the environment (see Section XX of this preamble).

HWIR, however, did not adopt the 1% total organic content criterion used in the LDR program. We thought it unnecessary to cap organic content for the purposes of selecting appropriate exemption levels. We presume that liquids exempted under HWIR would be managed in surface impoundments and aerated tanks independent of the organic content of the waste.

In contrast, the LDR program sought to distinguish wastes on the basis of treatment. By instituting a 1% cap on organic content, the LDR program could distinguish wastes likely to be treated by distillation or combustion from waste containing minimal organics less suited to these treatment technologies and more suited to more typical treatments for wastewaters (for example, biological degradation) (51 FR 1726). Therefore, the criteria based on organic content is more appropriate for the consideration of treatment technologies than for disposal destinations.

As a result of these two sets of definitions, there will be wastes that would be identified as ''liquid'' for the purposes of the HWIR exemption, and as ''nonwastewaters'' for the purposes of LDRs. However, ''liquid nonwastewaters'' is a meaningful term, representing organic liquids, and is generally recognized as a waste category distinguishable from more traditional wastewaters, both in terms of treatment alternatives and environmental concerns. Once understood, we do not believe that the presence of these two sets of terms will create difficulties for the regulated community.

We request comment on the waste form categories discussed for the HWIR generic option. Specifically, we request comment on the definition of (1) liquid (TSS<1%), (2) semi-solid (1%≤TSS≤30%) and (3) solid (TSS>30%); on the grouping of risk results based on specific waste management units that correspond to the three waste forms; and on the use of a conversion factor of one kg/L to convert the aerated tank and surface impoundment results (mg/L) for comparison to the land application unit results (mg/kg) in the semi-solid category.

In contrast to the generic option, wastes exempted under the landfill-only option would require exemption levels based only on the landfill destination and there is no need to segment the waste universe. HWIR implementation provisions would require that such waste be managed in a landfill. In addition, acceptance criteria at the landfill (such as the general prohibition against managing liquids in a landfill) combined with adequate waste representation for landfills in the HWIR modeling, help ensure that the landfill specific risk levels would be appropriate for these waste forms.

Possible Revision to LDR Treatment Standards

XX. How Might EPA Use the Results of the HWIR Model To Revise the Hazardous Waste LDR Treatment Standards?

A. What Is the Statutory Basis for the RCRA LDR Treatment standards?

The statutory requirement for LDR treatment standards is to ''substantially diminish the toxicity of the waste or substantially reduce the likelihood of migration of hazardous constituents from the waste so that short term and long term threats to human health and the environment are minimized.'' [RCRA Section 3004(m)]. Before we could use the risk-based results of the HWIR model to revise the hazardous waste treatment requirements under the RCRA land disposal restrictions (LDR) program, we would have to determine if the results ''minimize threat'' to human health and the environment as required by the statute.

Our implementation of this requirement has evolved through a long series of rulemakings (51 FR 1611). The first LDR treatment standards were largely based on what technology could achieve. To avoid unnecessary treatment, however, we had also proposed to ''cap'' the technology based standards with risk-based screening levels. These levels were based on human health toxicity thresholds for individual hazardous constituents and modeling of the groundwater route for exposure. (51 FR 1611–13.)

In the final initial LDR rule, we promulgated only the technology-based standards. We explained that although we believed we had the authority to promulgate risk-based standards, we were not promulgating the proposed risk-based caps, because of extensive comments raising concerns about the scientific uncertainties of the risk analyses performed to date (51 FR 40578). Members of industry challenged the final standards, claiming that they required treatment to concentrations below ''minimize threat'' levels. On review, the Court held that section 3004(m) authorized both technology-based and risk-based standards, but remanded the rule to EPA for a fuller explanation of our decision to rely on technology-based standards alone. (*Hazardous Waste Treatment Council* v. *EPA*, 886 F. 2d 355 (D.C. Circ. 1989). (''HWTC III'').) The court also held that EPA was not obligated to adopt either the RCRA characteristic test levels or the Safe Drinking Water Act Maximum Contaminant levels (MCLs) as ''minimize threat'' levels, because neither ''purports to establish a level at which safety is assured or 'threats to human health and the environment are minimized'.'' (886 F. 2d at 363.)

In our response to the remand, we stated that the best way to fulfill the requirements of section 3004(m) would be to ensure that technology-based treatment standards did not require treatment of hazardous chemicals that posed only insignificant risks. (55 FR 6641, Feb. 26,1991). We explained, however, that we were not yet able to promulgate such levels. We believed that we lacked a reliable predictive model for groundwater exposure; needed to assess exposure scenarios for

air pathways; needed to consider impacts on ecological receptors; needed to develop additional analytic methods for hazardous chemicals; and needed to develop an approach for chemicals with threshold effect levels lower than detection limits. (Id. at 6642.)

In the same notice, we noted that the ''minimize threat'' language of section 3004(m) could reasonably be interpreted to require more protection than the ''normal subtitle C command that standards be those necessary to protect human health and the environment.'' (Id. at 6641.) We found that the many portions of the 1984 amendments stressing the inherent uncertainties of land disposal buttressed this interpretation. [See RCRA sections 1002(b)(7), 3004 (d)(1)(A), 3004 (e)(i)(A), 3004(g)(5)]. We also found support in the LDR legislative history. For example, the Senate amendment containing the ''minimize threat'' standards replaced a committee bill that only would have required treatment to be ''protective of human health and the environment.'' [See S. 757, Section 3004(b)(7), printed at S. Pep. No. 284, 98th Cong., 2nd Session 86].

Further, we noted that the levels we had been using in site-specific and waste stream specific contexts, such as clean closures, delistings, and no-migration petitions, would not necessarily be appropriate for generally applicable standards required to minimize threats to human health and the environment. (55 FR 6641, note 1.) We took the position that section 3004(m) does not require the elimination of every conceivable threat posed by land disposal of hazardous waste, citing a statement by Senator Chaffee that ''[i]t is not intended that every waste receive repetitive levels of treatment, nor must all inorganic constituents be reclaimed.'' 130 Cong. Rec. S.9179 (daily ed., July 25, 1984). (55 FR 6641, note 1.) Clearly we did not interpret the minimize threat language to require the elimination of all threats.

Since the outset of the LDR program, we have continued to develop and refine the risk assessments that are the basis of our regulatory decisions with respect to waste identification. In addition, the increased sensitivity of analytical methods has lowered achievable detection limits and more extensive biological data are available for development of benchmark criteria for assessing ecological risk. As a result, the universe of available health-based and ecological data has grown significantly, and the reliability of this information has improved. In developing the HWIR risk assessment, we now believe that, for some chemicals, we might soon have enough data and the necessary tools to establish risk-based levels on a national level that minimize threats to human health and the environment.

B. Why Do We Believe That the HWIR Risk Assessment Results Could Be Used To Revise the Waste Treatment Standards?

The HWIR risk assessment could be used to develop risk-based LDR levels for several reasons. First, the HWIR risk assessment significantly expands our ability to evaluate human and ecological risk as compared to our historic capability. For example, unlike previous analyses that focused solely on groundwater, the HWIR risk assessment evaluates the potential for waste chemical migration through the most significant environmental fate and transport pathways. Second, the 1999 HWIR risk assessment looks at the total impact of all those pathways, not just at each pathway individually. Finally, the HWIR risk assessment also includes the greatest number of ecological benchmarks ever used in regulatory development under RCRA. These factors suggest that the tools and analyses now exist to properly evaluate when threats to human health and the environment are minimized.

C. How Might the Risk-Based LDR levels Be Implemented?

Generally, an HWIR exemption level would replace an LDR numerical treatment standard (''LDR level'') if it is less stringent than the existing LDR level. In this case, we could directly use the new risk-based levels to replace existing LDR levels found in waste-specific treatment requirements listed in the table at § 268.40 and the Universal Treatment Standard (UTS) levels listed in the table at § 268.48. Setting risk-based LDR levels could help simplify the HWIR exemption. For those chemicals for which HWIR exemption levels replace LDRs, meeting the HWIR exemption would simultaneously satisfy LDR treatment requirements for those chemicals. This does not necessarily mean, however, that all of the applicable LDR treatment requirements would have been met for that waste code. LDRs could regulate more chemicals than those with revised risk-based standards. Before a waste can be land disposed, all chemicals identified in the LDR standards for that waste code must meet applicable LDR treatment standards.

For some chemicals, however, the HWIR exemption levels might be more stringent than the existing LDR numerical standards. In this situation, the LDR standards would not be replaced by the HWIR level. Otherwise, if HWIR exemption levels were mandated, generators would have to treat their waste below levels that are achievable using the best demonstrated and available technology, which is the basis for the LDR standards. If the waste meets the LDR levels but not the HWIR exemption levels, then LDR requirements would be satisfied, but the waste would remain hazardous.

This section reviews and addresses key issues within the LDR program that will influence how the HWIR risk assessment results would be specifically integrated with the LDR waste treatment standards. For instance: (1) HWIR identifies liquid, semi-solid, and solid exemption levels while the LDR program identifies wastewater and nonwastewater treatability groups; (2) HWIR risk numbers are based on totals analysis while LDR levels are based on totals analysis and the Toxicity Characteristic Leaching Procedure, or TCLP; and (3) HWIR exemption levels that replace existing LDR levels for certain chemicals might potentially impact other wastes subject to LDRs.

Waste Treatment Standards—Treatability Groups. When prohibiting a waste stream from land disposal, the LDR program identifies chemicals of concern that potentially pose a threat to human health and the environment. The LDR numerical treatment standards represent wastewater and nonwastewater [1] chemical levels that technologies can achieve when treating specific waste streams. As discussed in section XIX of this preamble, HWIR numbers apply to liquids, semi-solids, and solids, which is a related but not identical scheme of classification.

To attempt to resolve this potential difference and to simplify implementation, we could use the HWIR ''liquid'' number for the LDR wastewater number, and the lower of the ''semi-solid'' and ''solid'' numbers for the nonwastewater LDR number. As discussed in more detail below, this type of simple substitution scheme assumes that the HWIR exemption levels are higher than the current numerical LDR waste treatment standards to which they would be compared.

Some methodological issues will need to be addressed in pursuing this type of approach (or potentially in any similar

[1] For purposes of implementing the LDR treatment standards, as defined in § 268.2, wastewaters are wastes that contain less than 1% by weight total organic carbon (TOC) and less than 1% by weight total suspended solids (TSS). Nonwastewaters are wastes that do not meet the criteria for wastewaters.

approach). For example, the LDR definition of ''wastewater'' (less than 1% Total Suspended Solids (TSS) and less than 1% Total Organic Content (TOC)) does not precisely match the HWIR definition of ''liquid'' (less that 1% TSS). This means that some wastes with less than 1%TSS and greater than 1%TOC would be liquids under the HWIR definition but nonwastewaters under the LDR definition. We would need to resolve this type of translational issue and others that might arise during detailed analysis. We note, for this particular case, that ''liquid nonwastewater'' is a meaningful term that describes certain types of existing waste—organic liquids.

Waste Treatment Standards—Totals and TCLP Analysis. HWIR risk numbers are based solely on totals analysis while the LDR levels are based on both totals analysis (most organics) or the TCLP (metals). In cases where the current LDR levels and the results of the HWIR model are directly comparable (in other words, both sets of numerical standards are based on total concentrations), an existing LDR numerical standards could be replaced by the appropriate HWIR number if it is less stringent than the existing LDR standard. As discussed above, this change would be reflected in tables § 268.40 and § 268.48.

For the chemicals (such as metals, cyclohexanone, methanol, carbon disulfide) that have LDR requirements based on the TCLP, the comparison of HWIR exemption levels and LDR numerical treatment standards involves another level of complexity. This arises because the HWIR exemption levels would be based on total chemical concentrations in the waste, whereas the LDR treatment standards are based only on what leaches out of the treated waste matrix using the TCLP test. For metals treatment standards that are based on stabilization, the TCLP test is typically used because the chemicals are not destroyed by treatment; they are only immobilized. The route of exposure is via leaching over time, which is measured by the TCLP. A totals test is not valuable for determining the leaching potential of these metals because it would also measure the chemicals that are immobilized.

To address this issue, we could give the hazardous waste generator the choice of meeting either the current leachate or the new totals number to satisfy LDRs. If a waste meets current leach numbers, but cannot meet the totals number, then it would meet LDRs, but it would not be eligible for an HWIR exemption. Table 11 below summarizes how we would integrate HWIR exemption levels (totals analysis) with LDR waste treatment standards (totals and TCLP analysis). We request comments on this suggested approach.

TABLE 11.—INTEGRATING HWIR EXEMPTION LEVELS WITH LDR WASTE TREATMENT STANDARDS

If the existing LDR treatment requirement for a particular chemical is based on	And if the HWIR exemption level for that chemical is	Then the LDR treatment requirement for that chemical
Totals analysis	More stringent than existing LDR level	Would remain the existing LDR level.
	Less stringent than existing LDR level	Would be revised to the HWIR exemption level.
TCLP	Either more or less stringent (that is, it doesn't matter which).	Would be satisfied if either the existing LDR level (TCLP) or the HWIR risk level (totals) is met.

Waste Treatment Standards—Applying Risk-Based LDR Levels. In cases where the current LDR levels and the results of the HWIR model are directly comparable, the appropriate HWIR number would become the LDR treatment standard for a chemical if it is less stringent than the existing LDR treatment standard. As stated earlier, this change would be specified in the waste-specific treatment requirements at § 268.40 as well as the UTS table at § 268.48. Therefore, these chemical-specific, risk-based LDR levels would apply to all hazardous wastes that must meet LDRs before they are land disposed.

This approach would alter treatment requirements for some characteristic wastes and underlying hazardous chemicals whose standards are based on totals analysis and that must meet UTS before land disposal. It would not affect wastes for which the LDR requirements are non-numerical and specify a treatment technology. This approach would also not affect any of the other LDR requirements, such as notification. Because HWIR is being handled on a chemical basis, the resulting suite of LDR numerical treatment standards could be a mix of original UTS and risk-based levels. One implementation question is whether there is a need to indicate which treatment standards have changed due to HWIR (for example, by asterisks in the part 268 tables).

Waste Treatment Standards and HWIR Exemption Requirements—Compliance Issues. We expect that some wastes can be treated to achieve more stringent levels than the existing LDR levels. The numerical UTS standards were calculated with a variability factor to take into account process variability on a national basis (*see* 51 FR 40591, November 7, 1986). We designed the variability factor to ensure that the LDR treatment standard was achievable in a wide variety of settings. However, on a site-specific or waste-specific basis, a generator might be able to achieve more stringent HWIR exemption levels if their own process variability is less than we have presumed in setting national standards. Thus, one issue is whether and how to develop the regulatory scheme when an HWIR level is more stringent than an LDR level for certain chemicals. If a generator could meet the more stringent HWIR exemption levels, and the generator fulfills the other requirements of the HWIR exemption, then the waste would become exempt from RCRA Subtitle C. Table 12 illustrates how a waste stream could satisfy HWIR exemption levels and LDR requirements simultaneously.

TABLE 12.—APPLICATION OF HWIR EXEMPTION LEVELS AND LDR TREATMENT STANDARDS

If all chemicals identified in a listed waste code	And all chemicals regulated in the listed waste code's LDR prohibition	Then the waste
Meet HWIR exemption levels and the generator fulfills the other requirements of the HWIR exemption.	Meet applicable LDR treatment standards	Would be exempt from Subtitle C regulation.

TABLE 12.—APPLICATION OF HWIR EXEMPTION LEVELS AND LDR TREATMENT STANDARDS—Continued

If all chemicals identified in a listed waste code	And all chemicals regulated in the listed waste code's LDR prohibition	Then the waste
Meet HWIR exemption levels and the generator fulfills the other requirements of the HWIR exemption.	Do not meet any applicable LDR treatment standards.	Would not be a hazardous waste but must meet LDR treatment standards before it can be land disposed.
Do not meet HWIR exemption levels or other requirements of the HWIR exemption.	Meet applicable LDR treatment standards	Would satisfy LDR treatment requirements but still be a hazardous waste and would have to be managed in a Subtitle C unit.
Do not meet HWIR exemption levels or other requirements of the HWIR exemption.	Do not meet applicable LDR treatment standards.	Would have to be treated to at least meet LDR treatment standards and be managed in a Subtitle C unit.

This regulatory approach only applies when the HWIR waste does not meet the exemption levels at the point of generation. As explained in section X.C, wastes that meet the HWIR exemption requirements at the point of generation are considered to never have been hazardous and therefore LDR requirements do not apply.

D. What Other Issues Would EPA Consider Before Setting Risk-Based LDR Standards?

Assuming that the methodological issues discussed above can be resolved satisfactorily, several other issues would need to be considered and resolved before we could set risk-based LDR treatment standards. Three issues relate directly to the ''minimize threat'' standard underlying the LDR treatment standards. These issues are: (1) Which risk protection criteria to use, (2) how to consider ecological data, and (3) how to consider inhalation and ingestion data. A fourth issue is how these changes to the UTS would affect the alternative soil LDR treatment standards.

As explained in Section XIX.A. of this preamble, we are evaluating four different combinations of values for the five different risk protection criteria. The five risk protection criteria are (1) risk level, (2) human health hazard quotient (HQ), (3) ecological hazard quotient, (4) population percentile, and (5) probability of protection. The final HWIR numbers could be based on any of the four combinations, or on another combination altogether.

If we were to use the results of the HWIR risk assessment to revise the LDRs, we would have to make sure that the risk protection criteria we choose are appropriate for both purposes, *i.e.*, met the risk protection criteria for HWIR and the minimize threat standard for LDR treatment standards. Although it is technically possible to chose separate criteria for the HWIR exemption and the LDR standards, much of the utility of setting risk-based LDR levels would be lost if they were set at a different level than the HWIR exemption.

The second issue, the need to address ecological risk, is one of the major gaps that we identified in our response to the court remand regarding the choice of risk-based or technology-based treatment standards (55 FR 6641). As explained in Section XVI.F of this preamble, the HWIR risk assessment includes a thorough evaluation of ecological effects for those chemicals with ecological health benchmarks. However, not all chemicals have ecological health benchmarks available. Some of these chemicals, which are not very persistent or bioaccumulative, would probably not be driven by ecological risk, while others would have an unknown effect on ecological receptors. For those chemicals that do not have readily available ecological data, we would need to decide if we should proceed with setting risk-based LDR levels using human health data and then revise them in the future when and if ecological data are available.

The third issue, the need to address risks from the air pathway in addition to the traditional groundwater ingestion pathway, is another gap we identified in our response to the court. As explained in Section XVI.E of this preamble, we have thoroughly evaluated the air pathways, both direct and indirect, for chemicals that have inhalation benchmarks. Unfortunately, not all chemicals have inhalation benchmarks, but some of these chemicals are not volatile, or have data showing negligible inhalation risk. Before setting risk-based LDR levels, we would have to decide how to deal with chemicals that lack inhalation risk benchmarks.

A fourth issue is how a change to the UTS tables to incorporate HWIR exemption levels would affect the alternative LDR soil treatment standards. Our alternative LDR treatment standards for soil allow regulated chemicals in soil to meet either a final concentration of (1) 10 times the current UTS, or (2) 90 percent reduction of the regulated chemical's initial concentration. (See 63 FR 28751, May 26, 1998) These alternative soil treatment standards are not mandatory—contaminated soils may still meet treatment standards developed for process wastes—but they are expected to provide greater flexibility when cleaning up contaminated soils subject to LDRs. For instance, the alternative soil treatment standards take into account (1) the matrix effect of the soil, which makes treatment difficult, and (2) the need to encourage clean-ups, thus minimizing the overall risk of the contaminated soil at the clean-up site. In fashioning this rule, we are seeking to maintain the benefits from the alternative soil standards and to create an implementation scheme that is simple and effective. We request comment on whether and how to use the results of the HWIR model to revise LDR treatment standards for soils, and on any implementation impacts flowing from our suggested approach.

Several issues arise when determining how a change in the UTS table due to HWIR exemption levels would impact the effectiveness and applicability of the alternative soil treatment standards. For instance:

- How should we integrate the HWIR exemption levels with the alternative soil treatment standards if the HWIR risk-based number is (1) greater than the UTS but less than 10xUTS and (2) greater than both the UTS and 10xUTS?
- How should we consider the HWIR exemption levels in for contaminated soil—for example, should we just apply the same 10x multiplication factor to the HWIR risk-based number? If so, is this consistent with the risk basis of the HWIR exemption levels? If not, will the HWIR exemption levels deter clean ups, which itself has the potential to minimize risks in a more global sense?

We would integrate the HWIR exemption levels with the soil treatment standards in a manner that preserves the advantages of the alternative soil treatment standards adopted in the recent Phase IV rule (63 FR 28751, May

26, 1998). We presume, strictly for purposes of presenting this discussion, that existing UTS numerical standards for process waste would be modified by HWIR exemption levels and that the result would be a set of revised UTS levels. Therefore, for purposes of this discussion, ''current UTS'' refers to existing technology-based UTS while ''revised UTS'' refers to UTS levels that would already have been modified to reflect HWIR risk-based exemption levels.

Under this scenario, when applying the soil treatment standards to treat constituents of concern present in contaminated soil, the constituents of concern may meet (1) the revised UTS, (2) 10 times the current UTS, or (3) 90% reduction of initial constituent concentration, whichever is greater.

This would not change implementation of the current soil treatment standards. Rather, it would make the soil treatment standards somewhat more flexible by providing that contaminated soils can meet the revised UTS LDR treatment standard in the case where the revised UTS is higher than 10 times UTS or 90% reduction. To implement this, we would add a table to the soil treatment standards with the chemicals and the specific alternative UTS levels (either the revised UTS or, if higher, 10x current UTS) for those chemicals.

We would not raise the current soil treatment standards to 10 times the HWIR exemption levels because such levels would no longer be minimize threat levels and could be greater than demonstrated performance levels. As mentioned earlier, if the HWIR exemption levels are below *both* the UTS and 10xUTS, we would not consider lowering the UTS. Lowering the UTS in this case would require generators to treat below levels that are achievable using the best demonstrated and available technology, which is the basis for the LDR standards.

Finally, when addressing the potential impacts of HWIR exemption levels on contaminated soils subject to LDRs, we would consider how the HWIR exemption levels could affect (1) the site-specific, contained-in determination, and (2) the site-specific, risk-based treatability variance developed specifically for contaminated soils (referred to as the risk-based soils variance). Both the contained-in determination and the risk-based soils variance apply site-specific risk-based numbers in their decision-making process. The potential might exist to compare national HWIR risk-based exemption levels to the site-specific risk-based numbers generated for a contained-in determination or risk-based soils variance. However, we intend that national HWIR exemption levels should not affect site-specific risk-based levels determined for either the contained-in determination or the site-specific risk-based treatability variance.

The contained-in policy is the basis for EPA's longstanding interpretation regarding application of RCRA Subtitle C requirements to mixtures of contaminated media and hazardous wastes. Under this policy, EPA requires that soil (and other environmental media), although not wastes themselves, be managed as if they were hazardous waste if they ''contain'' hazardous waste. Environmental media may contain hazardous waste if it is contaminated by a listed waste or exhibits a characteristic of hazardous waste. In practice, EPA has applied the contained-in principle to determine, on a site-specific level, that environmental media should no longer be regulated as hazardous waste because it does not ''contain'' hazardous waste.[2] This determination, referred to as a contained-in determination, is made by a regulatory agency and reflects conservative, health-based levels derived assuming direct exposure pathways. (See 63 FR 28621–28622). We expect that this tailored, site-specific determination would have precedence over national HWIR exemption levels.

Similarly, the risk-based treatability variance provides a way to establish alternative LDR treatment standards based on site-specific risk-based levels that are approved through the variance process. These risk-based levels reflect site-specific conditions, including information on (1) constituents of concern, (2) potential human and environmental receptors, and (3) potential routes of exposure. Again, we expect that this tailored, site-specific determination would have precedence over national HWIR exemption levels.

[2] Environmental media (e.g., soil) no longer contains hazardous waste when a site-specific determination is made that concentrations of hazardous constituents in any given volume of environmental media are low enough to determine that the media does not contain hazardous waste. Typically, these ''contained-in'' determinations do not mean that no hazardous constituents are present in environmental media but simply that the concentrations of hazardous constituents present do not warrant management of the media as hazardous waste.

Economic Impacts

XXI. What Are the Economic Impacts of Today's Proposed Regulatory Changes?

A. What Are the Economic Impacts of the Revisions to the Mixture and Derived-From Rules?

Today's proposal involves two revisions to the mixture and derived-from rules. The first applies an existing exemption for mixtures to waste derivatives and any hazardous waste that is listed solely because it exhibits one or more of the characteristics of ignitability, corrosivity, or reactivity. The second involves a conditional exemption for mixed radioactive hazardous waste managed under a new regulation being proposed in a separate Federal Register notice today. The economic impacts of the separate proposed mixed waste regulation are discussed in that Federal Register notice published elsewhere today.

The economic impact of the revision to the mixture and derived-from rules concerning wastes listed solely for a characteristic is discussed here. Additional information can be found in the *Economic Assessment of the U.S. EPA's 1999 Proposed Hazardous Waste Identification Rule (HWIR).* As discussed in Section IV of this preamble, there are currently 29 hazardous waste codes within the RCRA program listed solely for ignitability (I), corrosivity (C), and/or reactivity (R) characteristics. Today's proposed rule would exempt these wastes from RCRA Subtitle C regulation, if such wastes are de-characterized and meet the associated LDR treatment standards.

To estimate the potential economic impact of exempting these 29 characteristically-listed RCRA waste codes, we analyzed the type and quantity of industrial hazardous wastes contained in the two databases that underlie the HWIR Economic Model: the 1986 ''Generator Survey'', and the 1996 ''National Hazardous Waste Constituent Survey''. This model and these two databases are described in the Economic Assessment background document.

This exemption is expected to benefit the relevant segment of the RCRA regulated community by reducing the cost of shipping and disposing these de-characterized wastes. This potential cost savings is modeled in this study as consisting of two components:

(1) The difference between the cost for disposal of treatment residuals from these 29 waste codes in hazardous landfills (i.e., current or ''baseline'' practice), compared to the cost for

disposal in nonhazardous landfills under this exemption.

(2) The reduction in burden hours and associated burden cost for no longer requiring preparation, transmitting and filing of truck shipment hazardous waste manifests (EPA Form 8700–22) for these potentially exempt wastes.

The database extractions, computations and findings of the impact analysis are presented in the Economic Assessment background document. The highlights of U.S. EPA's estimated economic impacts for this HWIR provision are as follows:

—236 applicable industrial hazardous waste streams, totaling 3.6 million tons in annual generation by an estimated 120 US facilities.
—As generated, these waste streams consist of 87% wastewaters and 13% non-wastewaters.
—The 3.6 million annual tons quantity of applicable waste, represents 1.4% of the total RCRA hazardous waste universe (1993 BRS large generator total quantity = 258 million tons).
—Approximately 75% of the potentially exempt waste streams are identified by waste code F003 (spent non-halogenated solvents) plus a characteristic waste code (for example, D001), and 19% are identified by waste code F003 only.
—Applicable waste streams are located in 17 four-digit level SIC code industry sectors. 146 (62%) of the 236 applicable waste streams are generated by industries in SIC 28 (i.e. NAICS code 325).
—There are 51 different hazardous chemical constituents in the wastestreams; prevalent ones include: ethylbenzene, toluene, methyl ethyl ketone, methanol, ethyl acetate, xylenes, acetone, methylene chloride, and n-butyl alcohol.
—After RCRA Subtitle C treatment (mainly incineration), the 236 wastestreams result in the annual disposal of about 57,400 tons of treatment residuals, primarily in the form of incineration ash.
—Potential annual industry waste treatment residual, disposal cost savings is estimated at $4.593 million, while annual reduction in truck shipment manifesting cost is estimated at $0.455 million (i.e. 54,700 tons/yr divided by 20 tons/shipment = 2,870 manifests per year; 1.3 hours per manifest x $122 per hour x 2,870 manifests = $0.455 million). These two cost savings components represent a total annual cost savings estimate of $5.048 million. Applying −15% to +30% cost estimation uncertainty to this point-estimate (as explained in the background document), produces the associated cost savings estimation uncertainty range of $4.29 to $6.56 million per year.

B. How Would EPA Assess the Impacts of the HWIR Exemption?

Because we have not developed exemption levels, we have not estimated the potential economic cost impacts of the HWIR exemption. In addition, because the HWIR exemption is deregulatory by design, it will provide cost savings to industries with HWIR-eligible wastestreams. Before we would go final with an HWIR exemption, we would first publish an HWIR proposal that would include specific exemption levels and give the public an opportunity to comment. We would provide estimates of potential industry cost savings at that time as well.

The Economic Assessment describes a computer-based economic model we developed for the purpose of systematically estimating potential (a) type and quantities of HWIR eligible wastestreams, (b) industry implementation costs, and (c) net industry cost savings, once HWIR exemption levels are developed. [see *Economic Assessment of the U.S. EPA's 1999 Proposed Hazardous Waste Identification Rule (HWIR)*].

The Economic Assessment report describes the databases and decision-rules imbedded in this model, which includes a new database of industrial hazardous waste constituent identities and concentrations, based on 1996 survey questionnaires received from a sample of 156 hazardous industrial waste generator and handler facilities (reporting constituent data on 1,020 waste streams), administered by U.S. EPA's Office of Solid Waste (OSW). The data and findings of this ''National Hazardous Waste Constituent Survey'' (NHWCS) are also described and referenced in the Economic Assessment background document, as well as available for public review from the RCRA Docket in support of this proposal. The model integrates OSW's 1986 National Survey of Hazardous Waste Generators, and Treatment, Storage, Disposal, and Recycling Facilities, containing sample data for 8,016 industrial wastestreams associated with 4,036 facilities, with the new database.

Depending upon the types and number of constituent exemption levels developed, net cost savings are expected from industry switching the current management of low-risk wastestreams as RCRA hazardous wastes, to nonhazardous waste management practices after HWIR exemption, after netting-out industry HWIR implementation costs. Under the specific paperwork preparation and reporting requirements, and waste sampling/testing requirements outlined in this preamble (and as itemized in the Economic Assessment report), we estimate that the cost to industry for implementing HWIR will range from about $6,000 to over $50,000 per facility, depending upon the size and number of hazardous waste streams per facility and the number of HWIR-applicable constituents. This implementation cost estimate is based upon a preliminary average annual burden of 15 hours per facility for HWIR-related paperwork and reporting and a U.S. national average unit cost for waste sampling ranging from $150 to $900 per sampling event and per chemical (cost depends upon the chemical analyzed). These implementation costs would be offset with the potential cost savings and burden reduction of reduced waste management and disposal costs, as well as other RCRA hazardous waste related paperwork burden. As we move forward with HWIR, we will characterize the full economic impacts and Information Collection Request (ICR) burden of that proposal.

C. How Would EPA Assess the Impacts of the Possible LDR Revisions?

In Section XXI of this preamble, we discuss replacing the existing, technology-based LDR standards with HWIR exemption levels. Most of the LDRs prescribe constituent concentration non-exceedance thresholds, while some prescribe allowable treatment technologies (40 CFR 268.40 & 268.48). Without actual HWIR exemption levels to compare with the existing LDR levels, the potential economic effect (i.e. net decrease in average annual waste management costs to industry) is indeterminate. Costs savings from avoided treatment requirements would be highly variable, depending on which treatments are involved. Treatment costs are further discussed in the Economic Assessment document. As we move forward and propose the HWIR exemption, we will characterize the economic impacts of these regulatory provisions.

Relationship to Other Programs

XXII. How Would the HWIR Exemption Relate to Other Programs?

Today's notice discusses specific conditions and exemption criteria that would exempt listed hazardous wastes, including waste mixtures and derived-

from wastes, from RCRA Subtitle C regulation. A discussion of how these changes would affect other relevant RCRA regulatory programs is presented below.

A. Would HWIR Change How You Determine if a Waste Is Hazardous?

No, the HWIR exemption applies to listed hazardous wastes meeting exemption criteria, and it does not change the general requirements that you use to determine if a waste is hazardous. Under current RCRA regulations, if you generate a solid waste, you would have to determine if it is a hazardous waste as explained in 40 CFR 262.11 (Hazardous Waste Determination). You would have to first determine if your waste is excluded from regulation under 40 CFR 261.4 (Exclusions). Then you would have to determine whether your waste is listed in Subpart D of 40 CFR Part 261 (Lists of Hazardous Wastes), and/or the waste exhibits a characteristic defined in Subpart C of 40 CFR Part 261.

B. Could a Characteristic Hazardous Waste Be Exempt Under HWIR?

No. A waste that met all the HWIR exemption levels could nevertheless still be hazardous for a characteristic. You would have to still determine whether the waste exhibits any of the ignitability, corrosivity, reactivity or toxicity characteristics of a hazardous waste as specified in 40 CFR 261.21 through 261.24. If so, your waste continues to be hazardous until it no longer exhibits any hazardous waste characteristic.

C. How Would the HWIR Exemption Differ From the Delisting Process per 40 CFR 260.22?

In the delisting process, you would submit information to the State or Regional authority that your specific listed hazardous waste does not meet the criteria for which it was listed, and that the waste is not hazardous for any other reason (see 40 CFR 260.22). Until the State or Region makes an affirmative decision that your waste is delisted, your waste remains hazardous. In contrast, the purpose of the HWIR exemption is to establish a self-implementing rule where the hazardous waste generator, rather than the State or EPA, determines whether a listed waste would have to continue to be managed as a hazardous waste.

The evaluation criteria used for delisting vary from today's exemption criteria for the following three reasons: (1) Delisting is an interactive process with considerable oversight by us or authorized State agencies. In delisting, we evaluate the processes generating a specific waste stream to determine the chemicals likely to be present, as well as the potential variability in the waste. We closely review sampling procedures, analytical test results, and the accompanying QA/QC data. (2) Delisting is specific to one waste stream. For example, in a delisting petition you will typically provide the annual waste generation volume. Using a specific waste volume as an input to various models could result in delisting levels that are higher than the levels that would be developed with the HWIR model, which is based on a distribution of waste volumes that includes very large waste streams. We believe that it is reasonable to use higher exemption levels for the smaller waste volumes in delisting petitions, since these volumes pose less total risk than larger volumes of waste. (3) Delisting also considers the applicability of available groundwater monitoring data from land-based waste management units that have received the petitioned waste. Such data are typically required under permitting regulations for hazardous waste facilities. If any groundwater contamination appears to be due to chemicals from the petitioned waste, we will consider this as a basis to deny the petition.

We might also require special testing regimes when making delisting determinations to ensure waste consistently meets delisting criteria. A facility that accepts and treats waste from diverse sources would typically have frequent testing requirements. In other cases, the testing requirements for some initial period will be extensive, but the subsequent testing might be reduced.

Delisting petitions for wastes that contain chemical concentrations which exceed HWIR exemption levels, would continue to be accepted and reviewed by us after promulgation of today's rule. We do not anticipate any changes in the current review of delisting petitions as a result of the implementation of today's exemption.

D. How Would HWIR Affect TSDF Closure Requirements for My Facility?

If your TSDF accepts HWIR waste, the closure requirements might change, depending upon the waste management unit and the waste. If your hazardous waste management unit receives only waste that is exempt under today's proposal, it would no longer be receiving hazardous waste upon the effective date of the exemption. Thus, at that point in time, your TSDF would normally become subject to RCRA Subtitle C closure requirements, which are triggered by the final receipt of hazardous waste by the unit. You would be required to complete closure activities within 180 days after receiving the final volume of hazardous waste. (See *Time Allowed for Closure* in 40 CFR 264.113(b) and 265.113(b).)

However, RCRA closure requirements would allow you to delay closure of your waste management units, while continuing to receive HWIR waste, if you meet certain conditions. You may delay closure of landfills, land treatment units, and surface impoundments in cases where your unit stops receiving hazardous waste if you wish to continue using the unit to manage only nonhazardous waste. These requirements are outlined in 40 CFR 264.113(d) and (e) and 265.113(d) and (e). If you wish to delay closure, you would have to request a permit modification at least 120 days prior to final receipt of hazardous wastes, or, if the facility is in interim status, submit an amended part B application at least 180 days prior to the final receipt of hazardous wastes. The request for a permit modification or the amended part B application must include demonstrations that your unit has the existing design capacity to manage nonhazardous wastes, and that the nonhazardous wastes are compatible with any wastes in the unit. In addition, you must update facility information, including the waste analysis plan, groundwater monitoring plans, closure and post-closure plans, cost estimates, and financial assurance demonstrations, as necessary to account for receipt of only nonhazardous waste.

The delay of closure regulations apply only to landfills, land treatment units, and surface impoundments. In the case of other RCRA units such as tanks and waste piles, we do not believe that the delay-of-closure regulations are necessary for these units to receive only nonhazardous wastes. The closure requirements in 40 CFR Part 264 Subpart G (Closure and Post-Closure) for these units include removal or decontamination of waste residues, containers, liners, bases and contaminated soils, equipment, and other containment system components. These closure requirements are compatible with the reuse of these units for receipt of only nonhazardous waste. Once the unit has been emptied of all hazardous wastes and decontaminated, it could receive nonhazardous waste.

Delay of closure regulations do not, however, remove the final obligation for ensuring that a closed unit is protective of human health and the environment. For the 1995 HWIR proposal, we received comments requesting that we

allow units that have received only exempt wastes during the lifetime of the unit, including the time period prior to the effective date of HWIR, to be exempt from RCRA requirements, including closure. In effect, this would retroactively exempt the unit. Applying the HWIR exemption to waste that has already been disposed could, in theory, remove the RCRA Subtitle C closure requirements for that unit, because that unit would no longer contain hazardous waste.

However, we do not feel such an application of the HWIR exemption would be appropriate or practical considering the self-implementing nature of this rule. Ensuring that the already-disposed waste has been properly sampled and analyzed and is below the exemption levels in all cases would be problematic and would best be done with direct government oversight, as is done in delistings. Closure regulations provide important protections, such as evaluation of soil and groundwater contamination, that should not be lost because of a self-implementing waste identification rule.

E. How Would HWIR Affect the Land Disposal Restriction (LDR) Program?

Today's rule contains two important areas of overlap with the RCRA LDR program. First, we are asking comment on whether certain of the HWIR exemption levels should replace existing technology-based LDR standards, if the exemption levels are less stringent than the current LDR values.

Second, if your listed waste is below the HWIR exemption concentrations where the waste is first generated (the point where your waste first meets the listing description), then a hazardous waste is never generated and the LDR requirements do not attach to the waste. In contrast, once a listed waste is generated and managed, the LDR requirements attach, and remain even after the waste is exempted from RCRA Subtitle C under today's exemption.

In addition to these two areas of overlap, there is also the issue of whether you as an HWIR waste generator can ''partially exempt'' your waste, removing one or more waste codes, and thus simplifying LDR treatment while continuing to manage it as a hazardous waste. In concept, you would be able to demonstrate that concentrations for a subset of chemicals within your waste met HWIR exemption levels. By doing so, you would be able to remove one or more hazardous waste codes from your waste. Such ''partially exempted'' waste would continue to be managed as hazardous, but in some cases might have fewer LDR requirements or might have more disposal options (such as disposal in a unit whose permit restricts which waste codes can be accepted).

We have concerns about the feasibility of this approach and believe that the concentration-based exemption as discussed in this notice might not be well-suited to partial exemptions. A ''partial exemption'' would be difficult to implement using the self-implementing HWIR process. We designed the exemption to be a yes/no decision—if all concentrations of HWIR chemicals are at or below exemption levels, only then would waste be nonhazardous. Under this yes/no approach, we would not need a strict accounting of which hazardous chemical in the waste is associated with which waste code. In addition, we did not design the notification and other HWIR implementation requirements to take into account a ''partial exemption'' approach.

We are also concerned about possible confusion with respect to LDR requirements for a waste stream that has become ''partially exempt.'' Such waste is still considered hazardous and must meet LDR requirements if placed on the land. This gives rise to other questions. For example, if an individual waste code is removed, would the LDR treatment requirements associated with that waste code, including Universal Treatment Standards (UTS), continue to apply? Would compliance with LDR be a condition of such partial exemption? These and other implementation questions would need to be addressed.

Finally, we do not believe that any process removing hazardous waste codes should substitute for the exemption process as outlined in this notice. For example, a waste stream with one waste code could not pursue this partial exemption. We would want to ensure that a listed waste stream would still be regulated as hazardous until all the HWIR chemicals of concern were below risk-based concentrations, no matter from which waste stream they originated. We request comments on whether the HWIR exemption process could be adapted to allow the generator to removes specific waste codes from a waste that continues to be hazardous, and how such an adaptation would overcome implementation difficulties.

F. How Would HWIR Relate to the RCRA Air Emission Standards?

Currently, air emissions from units managing hazardous waste are regulated under 40 CFR Parts 264 and 265, Subparts AA, BB and CC. However, once your hazardous waste satisfies the HWIR exemption criteria (including any chemical-specific exemption concentrations for volatile organics, or VOs), it would be exempt from RCRA Subtitle C regulations, including these air emission standards. In other words, once a waste is no longer regulated as hazardous, any unit in which the waste is managed (assuming no other hazardous waste is managed in the unit) is no longer subject to RCRA Subtitle C regulations, including 40 CFR Parts 264 and 265, Subparts AA, BB, and CC.

However, we still would have to ensure that air emissions risks from HWIR wastes are adequately addressed. The final rule establishing air emission controls for tanks, surface impoundments, containers, and miscellaneous units (the ''Subpart CC'' regulations—see 40 CFR 264.1082) contains provisions whereby a hazardous waste is not subject to Subpart CC air emission controls requirements if the facility owner/operator demonstrates that VO concentration of the hazardous waste is below 500 ppmw (parts per million by weight).

Because exemption levels for specific volatile organics could in theory exceed the 500 ppmw threshold of the Subpart CC standards, we are requesting comment on whether the exemption would adequately address the air emission concerns of RCRA Section 3004(n) in allowing waste to become exempt from RCRA Subtitle C. One approach to address this concern would be to include an overall maximum cap for the sum of all VOs. Since Subpart CC doesn't apply to landfills, another approach would be to include a VO cap for the generic HWIR exemption, but not for the landfill-only HWIR exemption. We request comment on whether, to avoid undercutting the requirements of subpart CC, we should require HWIR waste to be below 500 ppmw for VO to address risks from volatile organics, and if so, whether this cap should be applied to the landfill-only HWIR exemption.

G. Would HWIR Affect ''Use Constituting Disposal'' Regulations?

The current 40 CFR 266.20 requirements for wastes used in a manner constituting disposal would not be changed due to the HWIR exemption at this time. Such a change is beyond the scope of our mandate to revise the mixture and derived from rules.

However, we are requesting comment on whether, in the future, we should revise 40 CFR 266.20 to make it more congruent to the HWIR exemption. Currently, 40 CFR 266.20(b) states that hazardous waste-derived products that

are legitimately recycled by being land-applied are exempt from RCRA Subtitle C regulation provided they satisfy three conditions: (1) the recyclable materials undergo a chemical reaction so as not to be separable by physical means, (2) the product must be produced for the general public's use, and (3) LDR standards for every hazardous waste in the hazardous waste-derived product must be satisfied. (The shorthand for this type of recycling is ''use in a manner constituting disposal.'' See 40 CFR 261.2(c)(1).)

The LDR standards, however, are technology-based rather than risk-based, and, for metal hazardous chemicals, only control leachable amounts of the metal. Yet in some situations, total metal levels might be more important than leach levels because of the possibility of direct contact through inhalation of abraded or wind-dispersed contaminants, or surface runoff. On the other hand, HWIR exemption levels would be risk-based and consider some of the exposure pathways similar to those relevant in analyzing uses constituting disposal (for example, inhalation of particles).

We solicit comment as to the appropriateness of applying HWIR exemption levels to hazardous wastes used in a manner constituting disposal. One approach would be to replace the requirement to meet LDR treatment standards with a requirement to meet the HWIR exemption levels. This approach should assure that exemption levels for hazardous wastes used in a manner constituting disposal are never less stringent than exemption levels for hazardous wastes placed in confined units. We request comment on the reasonableness of this approach.

H. Could Hazardous Waste Debris Become Exempt Under HWIR?

Hazardous debris that contains listed hazardous wastes would be eligible for the HWIR exemption. We note, however, that certain exemptions already exist relating to hazardous debris. On August 18, 1992, we published a final rule, Land Disposal Restrictions for Newly Listed Wastes and Hazardous Debris (57 FR 37194). In that rule, we required that hazardous debris be treated prior to land disposal, using treatment technologies from the treatment categories of extraction, destruction, or immobilization specified in 40 CFR 268.45, Table 1. We also added a conditional exemption at § 261.3(f) for non-characteristic hazardous debris (that is, debris that is hazardous solely because it contains listed hazardous wastes). Section 261.3(f)(1) exempts debris from RCRA Subtitle C regulation provided that the debris is treated using one of the extraction or destruction technologies specified in Table 1 of § 268.45. Alternatively, non-characteristic hazardous debris can be exempt under § 261.3(f)(2) if the Regional Administrator determines that it is no longer hazardous, after considering the extent of contamination of the debris, (in other words, after a ''contained-in'' determination is made). However, non-characteristic hazardous debris that is treated by a specified immobilization technology is *not* eligible for the conditional exemption in § 261.3(f)(1) and, therefore, remains subject to RCRA Subtitle C regulation after treatment.

We would not change the current exemption under § 261.3(f). Therefore, non-characteristic hazardous debris that requires LDR treatment by extraction or destruction technologies will be exempt from RCRA Subtitle C regulation, once treated. As was explained more thoroughly in the final rule for hazardous debris, we gave careful consideration to many factors before exempting certain treated debris, including whether each debris/contaminant type would be effectively treated by each BDAT technology to levels that would no longer pose a hazard to human health or the environment (57 FR 37240). We would also not change the contained-in exemption under § 261.3(f)(2) for hazardous debris. That is, the Regional Administrator may continue to determine on an individual basis that hazardous debris no longer contains listed hazardous waste, and should therefore be exempt from RCRA RCRA Subtitle C.

I. Would Contaminated Media Be Eligible for an HWIR Exemption?

Listed hazardous wastes generated from the remediation of contaminated sites are eligible for exemption under this rule. However, due to difficulty in characterizing the origin of these wastes, we request comment whether to require testing of an expanded list of chemicals for these wastes. We feel that generators might not have adequate knowledge of the history of these wastes to apply generator knowledge to determine which chemicals would reasonably be expected to be in such a waste. Also, field screening techniques used to identify contaminants might not detect chemicals at HWIR exemption levels. One option would be to require initial testing for all HWIR exemption chemicals.

J. Does the Final HWIR-Media Rule Impact HWIR?

No, although the HWIR-waste and the HWIR-media rules are often discussed together, and contaminated media are potentially affected by both rules, they are two separate rulemaking efforts on separate schedules. The HWIR-media rule does not address at what point wastes and media should become exempt from the RCRA Subtitle C regulatory system. Instead, HWIR media rule addresses other waste management issues, including permits, the storage of remediation wastes during cleanup and state authorization. The final HWIR-media rule was signed on November 30, 1998 (63 FR 65873).

K. How Would HWIR Impact Actions Under the Superfund Program (CERCLA)?

All RCRA F, K, P and U wastes are included under the definition of hazardous substances in CERCLA Section 101(14)(C). Under CERCLA Section 103(a), any person in charge of a vessel or facility must, immediately notify the National Response Center as soon as he or she has knowledge of the release, within a 24-hour period, of a reportable quantity (RQ) of any CERCLA hazardous substance. (See 40 CFR 302 for a list of these hazardous substances and their RQs.) If your waste met the HWIR exemption criterion, it would not be a hazardous waste and therefore not a hazardous substance as defined in CERCLA 101(14)(C). However, CERCLA does require a person in charge to notify the National Response Center of a release of the RCRA exempted waste if the waste or any of the chemicals of the waste are CERCLA hazardous substances by virtue of CERCLA Sections 101(14)(A), (B), (D), (E), or (F) or 40 CFR 302.4(b), and the waste or any of its chemicals that are hazardous substances are released in amounts greater than their RQs within a 24-hour period.

HWIR exemption levels may also be applicable to the CERCLA program where RCRA listed hazardous waste has been disposed at the site. CERCLA section 121(d) requires that CERCLA actions comply with, or justify a waiver of, applicable or relevant and appropriate requirements (ARARs) under federal and state environmental laws. The HWIR exemption could affect the legal applicability of federal RCRA requirements to remediation wastes generated at Superfund sites. They may also be considered in determining whether RCRA is relevant and appropriate in cases where it is not applicable.

At sites undergoing CERCLA remedial activities where no listed hazardous wastes have been identified, we use a site-specific risk assessment for chemicals that have no ARARs. In some cases, these health-based cleanup levels might be higher than the exemption levels, based on a reasonably conservative exposure scenario. In other cases, the CERCLA health-based clean-up levels might be lower than exemption levels. The CERCLA health-based clean-up levels may also be different from exemption levels based on the consideration of site-specific factors.

L. How Does HWIR Relate to the Draft Industrial D Voluntary Guidance?

EPA's Office of Solid Waste issued for comment the draft *Guide for Industrial Waste Management* (the Guide) in June 1999. The draft Guide is meant to provide decision-makers with recommendations and user-friendly tools to manage nonhazardous industrial waste protectively. The draft Guide contains reference materials and simple-to-use modeling tools to assess potential groundwater and air impacts. It gives stakeholders a common technical framework for planning and implementing a comprehensive industrial nonhazardous waste management system. The draft Guide is intended to be voluntary and non-regulatory. In contrast, HWIR will help determine which wastes are hazardous for the purposes of Federal regulation. Unit design, unit operation, and other aspects of hazardous waste management are mandated under RCRA Subtitle C regulatory oversight.

HWIR-exempt wastes are eligible for disposal in the industrial nonhazardous landfills, surface impoundments, waste piles and land application units discussed in the draft Guide. The draft Guide recommends tailoring protective liner systems to characteristics of the wastes and sites where they are managed, using a three-tiered approach to groundwater modeling and risk assessment. Each successive tier of analysis requires more specific data, from a minimum of waste characteristics to full-blown site assessment. The Guide provides user-friendly models for Tier 1 and 2 analyses. The Tier 1 model evaluates three liner scenarios: no-liner, single liner and composite liner. The Tier 2 model evaluates no-liner and single liner scenarios.

Because HWIR and the draft Guide were designed for different purposes, the modeling approaches also differ. We expect the greatest differences to arise from how the draft Guide handles risk modeling for lined impoundments, landfills, and waste piles. The draft groundwater model in the Guide incorporates assumptions for on-going liner performance that affect movement of leachate from the unit through subsurface soils to groundwater. The Guide also places strong emphasis on quality assurance/quality control for liners during installation, continued operation and maintenance to protect the liner, installation of final covers, and post closure care and monitoring. In the draft Guide, EPA is specifically requesting comment on how we can best model long-term performance of liners and final cover systems to ensure that users design systems that are protective of human health and the environment. The comment period on the draft Guide does not end until December 1999. We have not yet received comments on the draft Guide, as potential users are still reviewing the modeling tools and documentation.

HWIR has a different objective, to determine whether wastes are hazardous or nonhazardous. Since HWIR-exempt waste could be disposed in units without liners or other controls, the units that we model under HWIR are assumed to have no such controls. In addition there is considerable uncertainty about the long-term performance of controls even for units that do have them. Thus our hazardous waste identification policy has been to make the conservative assumption that such controls are not present for the purposes of risk assessment. We believe this is the most appropriate way to determine which wastes are low risk and should exit the Subtitle C regulatory program with this sort of self-implementing regulation. As we learn more about the long-term performance of liner and cover systems, EPA may decide to revisit this approach.

M. How Does HWIR Relate to the Comparable Fuels Exemption?

On June 19, 1998, EPA published air emission standards for hazardous waste combustion units (63 FR 338781). Under this final rule, we excluded, from the regulatory definition of solid waste, hazardous waste-derived fuels that meet specification levels comparable to fossil fuels for concentrations of hazardous chemicals. The exclusion applies to the comparable fuel from the point it is generated and is claimed by the generator of the comparable fuel. Fuel generators must comply with sampling and analysis, notification and certification, and recordkeeping requirements. The exclusion potentially applies to gaseous and liquid hazardous waste-derived fuels, but does not apply to solids or to used oil, which is subject to special standards under 40 CFR Part 279. The only allowable treatment or disposal method for a comparable fuel is burning.

Both the Comparable Fuels Exemption and the HWIR exemption require compliance with specified chemical concentrations levels, and both have similar, although not identical implementation requirements. The Comparable Fuels Exemption, however, is applied only to wastes with fuel value, and the levels were developed to be equivalent to chemical concentrations found in commonly-used fuels. HWIR, on the other hand, applies to all listed hazardous waste, and HWIR exemption levels would be developed based on a multimedia risk model. HWIR exemption levels would represent chemical concentrations that are acceptable to be managed in a nonhazardous waste unit. You may determine which exemption (if any) most fits your waste.

N. How Would HWIR Affect Mixed Waste?

Mixed waste is a combination of hazardous and radioactive wastes, and is simultaneously covered by RCRA and the Atomic Energy Act. Because HWIR would exempt some hazardous wastes from RCRA Subtitle C requirements, it might also, through the same process, exempt some mixed waste from the RCRA hazardous waste regulations (without affecting its status under the Atomic Energy Act) as well.

However, because of the overlap of federal requirements for mixed waste, we are also developing rules specifically related to mixed waste. As mentioned in Section II of this preamble, EPA is proposing a separate **Federal Register** notice to conditionally exempt hazardous waste mixed with low-level radioactive wastes or mixed with Naturally Occurring and/or Accelerator-produced Radioactive Material from the storage, treatment in storage tanks, transportation, and disposal requirements of RCRA when the waste is managed in accordance to the Nuclear Regulatory Commission (NRC) regulations. In addition, we are developing a regulation allowing disposal of mixed waste containing radionuclides at low activity levels at facilities meeting the design requirements for RCRA Subtitle C, with the NRC to be the implementing agency of this rule. More information on this proposal can be found in the most recent agenda of regulatory and deregulatory actions (64 FR 21987).

O. How Does HWIR Relate to the Sewage Sludge Regulatory Program?

Sewage sludge (biosolids) is a material Federally regulated under the authority of Sections 405(d) of the Clean Water Act (CWA), as amended (33 U.S.C.A. 1251, *et seq.*). On February 19, 1993, we published regulations to protect public health and the environment from any reasonably anticipated adverse effects of certain pollutants that might be present in sewage sludge (58 FR 9248). The regulations are codified at 40 CFR Part 503 with conforming amendments codified at 40 CFR Parts 257 and 403. Part 503 allows four means of final use or disposal of sewage sludge: land application, surface disposal, incineration in a sewage sludge incinerator, and disposal in a solid waste landfill. Part 503 establishes requirements for land application, i.e., placing sewage sludge on the land for a beneficial purpose (including sewage sludge or sewage sludge products that are sold or given away for use in home gardens), surface disposal, i.e., by placement on surface disposal sites (including sewage sludge-only landfills), and incineration. The standards for each end use and disposal practice consist of general requirements, numerical limits on the pollutant concentrations in sewage sludge, management practices and, in some cases, operational requirements. The Part 503 Rule also includes monitoring, record keeping and reporting requirements. Parts 257 and 258 govern disposal of sewage sludge in solid waste landfills.

The regulations promulgated under section 405(d) of the Clean Water Act apply to domestic sewage sludge, defined in Part 503 as ''solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes, but is not limited to, domestic septage; scum or solids removed in primary, secondary or advanced wastewater treatment processes; and a material derived from sewage sludge.''

Sewage sludge regulated under section 405 of the Clean Water Act is not hazardous waste. Under section 3001 of RCRA, solid wastes are ''hazardous'' either by being a ''listed'' hazardous waste or by exhibiting a ''characteristic'' of hazardous waste. We have not listed sewage sludge as a hazardous waste, nor has sewage sludge been found to exhibit any hazardous waste characteristic. However, a sewage sludge that met the definition of hazardous waste under 40 CFR Part 261 would be subject to hazardous waste regulations, and would not be within the scope of Part 503. (see 58 FR 9253).

Both the HWIR exemption and the sewage sludge regulations include numerical limits for certain chemicals. However, we do not expect the results of the two efforts to be the same, both because of different assumptions in the risk assessments and the differences in the physical and chemical characteristics of the matrices between sewage sludge and process waste— for example, sewage sludge has a higher organic content than process waste, and that tends to immobilize certain chemicals, such as metals—and because of the fact that the Part 503 program requirements are different. As stated earlier, the sewage sludge regulations consist of other requirements beyond numerical limits, including management practices and monitoring requirements. For additional information on the Part 503 program, the Part 503 regulation, and the multi-pathway exposure/risk assessment that serves as the technical basis of the Part 503 regulation, the reader is directed to the following Internet site: *http://www.epa.gov/owm*.

State Authorization

XXIII. How Would Today's Proposed Regulatory Changes Be Administered and Enforced in the States?

Under section 3006 of RCRA, EPA may authorize qualified States to carry out the RCRA hazardous waste program within the State. Following authorization, we maintain independent enforcement authority under sections 3007, 3008, 3013, and 7003 of RCRA, although authorized States have enforcement responsibility. An authorized State could become authorized for this proposal's regulatory changes by following the approval process described under 40 CFR 271.21. See 40 CFR Part 271 for the overall standards and requirements for authorization.

We are proposing to retain the mixture and derived-from rules. Most states have already received authorization for the mixture and derived-from rules as they currently stand. The rules are already in effect in those authorized States. Those states that are already authorized for the mixture and derived-from rules would not need to obtain authorization for those rules again. We are also proposing to revise those rules under the authority of sections 3001(a), 3002(a), and 3004(a) of RCRA. If promulgated, these revisions would not go into effect in authorized States until they adopt the revisions and receive authorization from us for the revision to their regulations.

None of the proposed revisions are more stringent or broaden the scope of the existing Federal requirements. Authorized States are not required to modify their programs when we promulgate changes to Federal requirements that are less stringent than, or that narrow the scope of, existing Federal requirements. This is because RCRA section 3009 allows the States to impose (or retain) standards that are more stringent than those in the Federal program. (See also 40 CFR 271.1(i)). Therefore, States would not be required to adopt the revisions to the mixture and derived-from rules in today's rule, although EPA would strongly encourage their adoption.

Administrative Requirements

XXIV. How Has EPA Fulfilled the Administrative requirements for this Proposed Rulemaking?

Several statutes and executive orders apply to proposed rulemaking. Below is an explanation of how to address the requirements in those provisions:

A. Executive Order 12866: Determination of Significance

Under Executive Order 12866 [58 FR 51,735 (Oct. 4, 1993)], EPA must determine whether a regulatory action is ''significant'' and, therefore, subject to OMB review and the other provisions of the Executive Order. The Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or rights and obligations or recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Pursuant to four term of Executive Order 12866, we have determined that this rule is a ''significant regulatory action'' because there are novel policy issues arising out of legal mandates. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the docket to today's proposal.

B. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996) whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant [adverse] economic impact on a substantial number of small entities.

SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. The following discussion explains our determination.

As discussed in Section XXI, we have prepared an economic analysis of the potential effects of this rule, and have determined that the rule is expected to have a net beneficial effect on eligible entities, in the form of reduced environmental regulatory compliance costs for industrial waste management. The economic analysis evaluates the extent to which both small quantity and large quantity industrial waste generators might be potentially eligible for cost savings under this rule. This proposed rule is voluntary, and the overall economic effect of this regulation for both small and large entities which are eligible to participate, is expected to be a net average annual reduction in industry regulatory burden and compliance costs. Consequently, because the net economic impacts and effects of this rule are beneficial rather than adverse, this rule will not have a significant [adverse] economic impact on a substantial number of small entities. *I hereby certify that this rule will not have a significant economic impact on a substantial number of small entities.* This rule, therefore, does not require a regulatory flexibility analysis.

C. Paperwork Reduction Act (Information Collection Request)

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 0801.12) and a copy may be obtained from Sandy Farmer by mail at OPPE Regulatory Information Division; U.S. Environmental Protection Agency (2137); 401 M St., S.W.; Washington, DC 20460, by email at farmer.sandy@epamail.epa.gov, or by calling (202) 260–2740. A copy may also be downloaded off the Internet at http://www.epa.gov/icr.

Today's proposed revisions of 40 CFR 261.3 do not include any new record keeping or reporting requirements. However, the proposed revisions could reduce the burden estimate for existing RCRA information collection requirements, such as the Uniform Hazardous Waste Manifest (Form 8700–22A). As discussed in Section XXII of this preamble, today's proposal could exempt approximately 54,700 tons of treated waste residuals (mainly incineration ash) per year. Assuming that these now-exempt wastes are shipped offsite for disposal, and assuming that an average truckload carries about 20 tons (of solids), today's proposal could result in approximately 2,870 shipments per year that would no longer require Uniform Hazardous Waste Manifest. The RCRA Hazardous Waste Manifest System ICR (No. 0801.12.) estimates an annual burden of 1.29 hours per shipment of hazardous waste. Therefore, today's proposal could reduce the total burden associated with manifests by 3,702 hours per year. (The current burden associated with manifests is estimated to be 2,920,383 hours per year).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

Comments are requested on EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, OPPE Regulatory Information Division; U.S. Environmental Protection Agency (2137); 401 M St., S.W.; Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., N.W., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Please refer to EPA ICR No. 801.12 and OMB Control No. 2050–0039 in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after November 19, 1999, a comment to OMB is best assured of having its full effect if OMB receives it by December 20, 1999. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, we generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes, with the final rule, an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, we must have developed under section 203 of the UMRA a small government agency plan. The plan must

provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's proposed revision to the mixture and derived-from rules is voluntary, and because is less stringent than the current regulations, State governments are not required to adopt the proposed changes. The UMRA generally excludes from the definition of ''Federal intergovernmental mandate'' duties that arise from participation in a voluntary federal program. The UMRA also excludes from the definition of ''Federal private sector mandate'' duties that arise from participation in a voluntary federal program. Therefore we have determined that today's proposal is not subject to the requirements of sections 202 and 205 of UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to the Office of Management and Budget (OMB), in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. For final rules subject to Executive Order 13132, EPA also must submit to OMB a statement from the agency's Federalism Official certifying that EPA has fulfilled the Executive Order's requirements.

This proposed rule is not subject to Executive Order 13132 because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This proposed rule will not result in the imposition of any additional requirements on any State, local governments or other political subdivisions within any State. Accordingly, the requirements of Executive Order 13132 do not apply to this proposal.

F. Executive Order 13084: Consultation and Coordination with Indian Tribal Governments

Under Executive Order 13084, we may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or we consult with those governments. If we comply by consulting, Executive Order 13084 requires us to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of our prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires us to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. Because today's proposed revision to the mixture and derived-from rules is less stringent than the existing program, it would not create any mandate on Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

''Protection of Children from Environmental Health Risks and Safety Risks'' (62 *FR* 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that we have reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, we must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by us. This proposed rule is not subject to E.O. 13045 because it is not an economically significant rule as defined by E.O. 12866.

H. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Pub L. No. 104–113, § 12(d) (15 U.S.C. 272 note) directs us to use voluntary consensus standards in our regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when we decide not to use available and applicable voluntary consensus standards.

Today's proposals do not involve technical standards. However, the HWIR exemption discussed in this notice does involve sampling and analysis requirements, but does not contemplate the use of specific, prescribed analytical methods. Rather, we would allow the use of any method that meets the prescribed performance criteria, consistent with our Performance Based Measurement System (PBMS). The PBMS approach is intended to be more flexible and cost-effective for the regulated community; it is also intended to encourage innovation in analytical

technology and improved data quality. We would not preclude the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the requirements and performance criteria specified. We welcome comments on this aspect of the notice and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used.

References

XXV. What Are Some Key Documents Containing Information Supporting This Notice?

The list of references is organized by the following preamble super-headings: (1) Background, (2) Retaining the Mixture and Derived-From Rules, (2) HWIR Exemption, (3) HWIR Risk Assessment, and (4) Economic Impacts. Under each super-heading, the references are listed alphabetically by author and chronologically when there is more than one document by the same author.

These references and other supporting information can be found in the RCRA Docket Information Center (see contact information under ADDRESSES section at the beginning of the preamble).

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Request for Comment

XXVI. On What Issues Is EPA Specifically Seeking Public Comment?

In developing this notice, we tried to address the concerns of all our stakeholders. Your comments will help us improve this rule. We invite you to provide different views on options we discuss, new approaches we haven't considered, new data, how this rule may affect you, or other relevant information. We welcome your views on all aspects of this notice.

Your comments will be most effective if you follow the suggestions below:

- Explain your views as clearly as possible and why you feel that way.
- Where possible, provide technical and cost data to support your views.
- If you estimate potential costs, explain how you arrived at the estimate.
- Tell us which parts you support, as well as those you disagree with.
- Provide specific examples to illustrate your concerns.
- Offer specific alternatives.
- Refer your comments to specific sections of the notice, such as the section numbers or page numbers of the preamble, or the proposed regulatory sections.

We welcome comments on any and all aspects of the rulemaking, and we are particularly interested in receiving comments on the issues listed below. For information on how to submit your comments, please see the **ADDRESSES** section towards the beginning of this preamble.

1. What are merits and drawbacks of the five possible revisions to the mixture and derived-from rules submitted to EPA by CMA? Specifically, what are (a) the potential risks to human health and the environment, (b) any special or unique technical considerations, and (c) the economic effects of each of the possible revisions? (Section II.E)

2. Should EPA allow F003 to be eligible for the proposed expansion of the 40 CFR 261.3(a)(2)(iii) exemption (although F003 is listed solely for ignitability, its listing description includes references to solvents that were listed for toxicity as well)? (Section IV.A)

3. Should EPA conditionally exempt low level radioactive hazardous mixed waste from the mixture and derived-from rules, provided the mixed waste is handled in accordance with the requirements of a new Part 266, Subpart N, which is being simultaneously proposed today? (Section IV.B)

4. Should EPA propose and finalize the landfill-only exemption (based on conditions of management) and the generic exemption (not based on conditions of management) from hazardous waste regulation? (Section VI)

5. Should the HWIR exemption be self-implementing? (Section VIII)

6. Should EPA require a waiting period between the receipt of the notification package by the overseeing agency and the time the waste becomes exempt (for example 30 to 90 days)? (Section VIII)

7. Is EPA's definition of ''chemicals reasonably expected to be present'' acceptable? In particular, should the definition be adjusted for some of the broader waste listings such as spent solvents (RCRA waste codes F001–F005)? (Section IX.A)

8. Is EPA's policy to exclude from HWIR eligibility those wastes are reasonably expected to contain chemicals that do not have HWIR exemption levels appropriate? If not, what are other options for dealing with chemicals that do not have HWIR exemption levels? (Section IXA)

9. Should EPA require a minimum number of samples at each sampling event? If so, what should that number be? (Section IX.B.2)

10. Is the use of the strict maximum standard (i.e., no sample is allowed to exceed the HWIR exemption level) appropriate for the evaluation of a waste stream for an HWIR exemption? If not, what is the preferred alternative? (Section IX.B.2)

11. Should EPA require that the bias introduced by partial recoveries of the chemicals under analysis be corrected in order to make results from different

analytical methods more comparable? (Section IX.B.3)

12. If EPA requires correction of the bias introduced by partial recoveries, should EPA require that analytical protocols achieve a minimum of 20% recovery, and that analytical results with analytic spike recovery of less than 100% be corrected for the percent recovery determined for that sample before being compared to the HWIR exemption level? (Section IX.B.3)

13. Should EPA use the detection limit in place of the HWIR exemption level when the detection limit is higher than the exemption level, but still within an acceptable level of risk? (Section IX.B.3.)

14. As an alternative to using the strict maximum standard for compliance, should EPA require that the upper confidence limit (set at some level of confidence, such as 95 percent) associated with the mean concentration in the candidate waste be at or below the HWIR exemption level for the waste to be HWIR exempt? (Section IX.C.1)

15. As a second alternative to using the strict maximum standard for compliance, should EPA require that the estimated mean chemical concentration within the candidate waste be at or below the HWIR exemption levels, and that the concentration of individual samples would have to be at or below some multiple of the exemption level? (Section IX.C.1)

16. As a third alternative to using the strict maximum standard for compliance, should EPA require that the estimated mean concentration be at or below the HWIR exemption level, and the upper confidence limit associated with the estimated mean (at some level of confidence) would have to be at or below some multiple of the exemption level? (Section IX.C.1)

17. For the regulatory alternatives that allowing individual samples to be at or below some multiple of the HWIR exemption levels, how should those limits (for example, multipliers to the exemption levels) be established? Specifically, should EPA use a multiplier of 2.8, consistent with the variability factor used in the LDR program? (Section IX.C.1)

18. Should EPA consider the use of composite samples, particularly spatial composites, in addition to grab samples, in evaluating a waste stream for HWIR compliance? (Section IX.C.2)

19. Should EPA specify the size of samples taken to evaluate a waste stream for HWIR compliance? (Section IX.C.2)

20. Is the sample notification form included in the docket (titled ''Sample Notification Form for Waste Claiming Exemption Under the Hazardous Waste Identification Rule'') adequate for claiming an HWIR exemption? (Section IX.D)

21. What alternatives to the written notification package should EPA consider (such as electronic submissions)? (Section IX.D)

22. Should EPA require additional information in the notification package, such as the list of chemicals found in the waste and a summary of results for each sample analyzed? (Section IX.D)

23. Are existing mechanisms for information sharing, including access via the Internet, sufficient to provide the public with information relative to individual HWIR exemption claims exerted in each respective State? (Section IX.E)

24. If existing mechanisms are insufficient, should EPA require HWIR waste generators to notify the public of HWIR exemption claims through a newspaper notices, prior to having the exemption claims become effective? (Section IX.E)

25. If EPA requires public notification through newspaper notices, should the receipt of adverse comments by the generator trigger review the HWIR exemption package by the overseeing agency? (Section IX.E)

26. Should EPA require HWIR waste generators to include testing results information in the notification package for the purpose of greater public access to this information? (Section IX.E)

27. Should EPA require that paperwork accompany the waste in order to track the waste and provide notice to the receiving facility that the waste is HWIR-exempt? (Section X.B.)

28. Should EPA prohibit dilution as a means of attaining the HWIR exemption levels? If so, should EPA allow aggregation of waste streams for the purpose of treatment in CWA wastewater systems? (Section X.C)

29. What are the advantages and disadvantages of requiring the same testing scheme for both initial and subsequent sampling and analysis of HWIR waste? (Section XI.A)

30. Should EPA allow the use of prediction limits and other such techniques for the purpose of subsequent testing? (Section XI.A)

31. Should EPA allow the removal of testing requirements for chemicals consistently detected in concentrations of less than one-tenth of the exemption level? If so, after how many testing events with levels below one-tenth of the exemption level should this reduced testing obligation occur? (Section XI.A.1)

32. Should the retesting frequency depend on (a) the annual volume of waste generated, and (b) the physical form of a waste (liquid or non-liquid)? Are there other factors EPA should consider when setting retesting frequency? (Section XI.A.2)

33. Should EPA reduce the testing frequency for generators who are small businesses (that may or may not generate large annual volumes of waste)? (Section XI.A.2)

34. Should EPA require retesting after a significant process change? (Section XI.A.3)

35. If a wastestream loses its HWIR-exempt status because it no longer meets the exemption levels or does not meet one of the other conditions of the exemption, should EPA impose additional requirements before the exemption can be reinstated? For example, should there be a mandatory waiting period before the exemption can be reinstated? (Section XII.B)

36. Should EPA prohibit storage of HWIR waste for longer than one year? (Section XII.B.2)

37. For the landfill-only option, should tracking of HWIR waste be limited to: notifying the landfill of the shipment; receiving a confirmation from the landfill that the waste arrived; and keeping a copy of the arrival confirmation for three years (first alternative)? (Section XII.B(3))

38. Under this first tracking alternative, should the landfill also be required to keep a copy of the arrival confirmation for three years as well?(Section XII.B(3))

39. For the landfill-only option, should tracking of HWIR waste consist of: using the existing uniform hazardous waste manifest system (40 CFR 262.20 and 49 CFR 172.205) to track the conditionally exempt HWIR waste (second alternative)? (Section XII.B.3)

40. For the landfill-only option, should tracking of HWIR waste consist of: using modified DOT shipping papers to accompany the waste; receiving a copy of the shipping papers documenting that the waste arrived at the landfill; and keeping a copy of these documents for three years (third alternative)? (Section XII.B.3)

41. How can EPA address the issue of interstate transport of HWIR waste, where waste exempted in one State would still be regulated as hazardous as it travels to or through a State that has not adopted the HWIR exemption? (Section XII.B.3)

42. Is the approach EPA has taken to account for mass balance and to integrate the calculations of the important direct and indirect risk pathways leading to a receptor appropriate? If not, what are alternative approaches? (Section XVI.A.2)

43. Is EPA's approach to evaluating the exposed and unexposed receptors appropriate? (Section XVI.A.2)

44. Is EPA's approach to modeling risk to humans from groundwater, considering the risk posed at receptor wells located within the modeled plume of contamination and outside the modeled plume of contamination reasonable? (Section XVI.A.2)

45. Are EPA's estimates of the fraction of the modeled wells located within and outside of the modeled plume of contamination reasonable? (Section XVI.A.2)

46. Is the methodology for selecting the 201sites to represent the national population of industrial facilities appropriate? If not, what are alternative methodologies? (Section XVI.A.3)

47. Should EPA apply the sampling weights from the Industrial D Survey to the sample of 201 sites? (Section XVI.A.3)

48. Does the information contained in the HWIR chemical database reflect the current state of knowledge for the chemical parameters ? (Section XVI.A.3)

49. Is there any additional information on the chemicals that EPA should consider? (Section XVI.A.3)

50. Is our information on anaerobic biodegradation (for example in the saturated zone) of organic chemicals sufficient? (Section XVI.A.3)

51. Is there any additional data on anaerobic biodegradation of organic chemicals? (Section XVI.A.3)

52. Should EPA use toxicity data, in addition to data contained in EPA's IRIS and HEAST databases, (a) which other Federal agencies have used in establishing regulatory levels or toxicity benchmarks, or (b) which have been otherwise peer-reviewed and published? (Section XVI.A.3)

53. If EPA uses toxicity data other than the data contained in EPA's IRIS and HEAST databases, is EPA's methodology to develop interim benchmarks from this other data appropriate? If not, what are alternative methodologies? (Section XVI.A.3)

54. Is EPA's decision to establish regulatory levels based only on the chemical-specific total concentration in the waste, rather than requiring wastes to meet both total and leachate levels appropriate?

55. In terms of establishing a relationship within the model between the chemical concentration in the waste and the chemical concentration in the leachate, and of mass limitations in leachate, should EPA (for each waste management unit) start with a chemical concentration in a waste and partition it to the various environmental media based on the physical and chemical characteristics of the chemical, the waste management unit characteristics, and the partitioning algorithms? (Section XVI.D.)

56. Are the methodologies used for modeling the environmental releases for HWIR99 appropriate? If not, what are alternative methodologies? (Section XVI.D)

57. Are the methodologies used for modeling the environmental fate and transport for HWIR99 appropriate? If not, what are alternative methodologies? (Section XVI.E)

58. Are the data and methodologies used to support the HWIR overall modeling framework appropriate? If not, what alternatives should EPA use? (Section XVI.E.1)

59. Are the methodologies that EPA plans to implement in the saturated zone module (SZM) in order to factor the effects of fractures in porous media and incorporate effects of heterogeneity in aquifers into the modeling appropriate? (Section XVI.E.3.A)

60. Is EPA's methodology for calculating infant exposure to dioxin and dioxin-like chemicals in breastmilk appropriate? If not, what are alternative methodologies? (Section XVI.F.1)

61. Should EPA model infant exposure to chemicals other than dioxin and dioxin-like? If so, which chemicals should be considered? (Section XVI.F.1)

62. Over which time period should exposure at a receptor be evaluated? (Section XVII)

63. Are there any revisions to the software system that would address identified errors or improve the risk model ? (Section XVII)

64. Is EPA's decision to model degradation processes, including hydrolysis, aerobic biodegradation, anaerobic biodegradation, and activated aerobic biodegradation appropriate? (Section XVII.B.2)

65. Is the toxicity of daughter products that may be generated from the degradation process of significant concern? If so, what methodology should be used to calculate the ratio of parent to daughter product for the purpose of the model? (Section XVII.B2)

66. Under which physical conditions should EPA assume that each of these degradation processes occurs? (Section XVII.B.2)

67. Should EPA either (a) prohibit the combustion of already exempt HWIR waste, or (b) implement a more targeted combustion restriction for HWIR exempt waste based on chemical content? If not, are there any other alternatives for addressing risks from the combustion of HWIR exempt wastes? (Section XVII.D.1)

68. Should EPA allow HWIR exempt wastes to be eligible for beneficial uses? (Section XVII.D.2)

69. Did EPA use adequate data to consider (a) the possibility that wastes with constituent concentrations low enough to qualify for exemption could result in free-phase migration of chemical compounds in groundwater, including the potential NAPL contamination of groundwater due to the formation of free-phase liquids in landfills and (b) the possible impacts of co-solvency on the migration of contaminants adequate? (Section XVII.D. 4.)

70. Is the toxicity characteristic adequate for capturing the risks from wastes derived from exempt liquids? (Section XVII.D.4)

71. Is the assumption that surface impoundments have waste removed at the time of closure likely to affect the results of the risk assessment? (Section XVII.D.5)

72. Are the chemicals in the new 40 CFR Part 261 Appendix X the best set of chemicals to be considered for the HWIR exemption? If not, which set of chemicals should be considered? (Section XVIII.A)

73. Are the sources of toxicity data that EPA considered adequate? If not, what other sources should EPA consider? (Section XVIII.B)

73. Should EPA establish an HWIR exemption level for lead based on the lower of two values: 400 mg/kg soil screening level for human health risks and on the results from the HWIR ''99 risk assessment for ecological risks? If not, what alternative would you recommend? (Section XVIII.C)

74. Which wastes would be impacted by the absence of an HWIR exemption level for cyanide? (Section XVIII.D)

75. How could an HWIR exemption level be set for cyanide, given its complex chemistry? (Section XVIII.D)

76. Which chemicals and waste streams are especially good candidates for HWIR exemptions? (Section XVIII.D)

77. Is the range of values that EPA considered for each of the risk protection measures appropriate? If not, what alternative values should be considered? (Section XIX.A)

78. For each of the risk protection measures (cancer risk level, human health hazard quotient, ecological hazard quotient, population percentile, and probability of protection), which single value is most appropriate? (Section XIX.A)

79. Is the HWIR definition of liquids (i.e., Total Suspended Solids (TSS) less than one percent) appropriate? (Section XIX.C)

80. Is the HWIR definition of semi-solids (i.e., TSS greater than or equal to one percent and TSS equal to or less than 30 percent) appropriate? (Section XIX.C)

81. Is the HWIR definition of solids (i.e., TSS greater than 30 percent) appropriate? (Section XIX.C)

82. As an alternative to defining solids as waste containing greater than 30% TSS, should the paint filter test be used to define the threshold between semi-solids and solids? (Section XIX.C)

83. Is the use of a conversion factor of one kg/L to convert the tank and surface impoundment results (mg/L) for comparison to the land application unit results (mg/kg) in the semi-solid category acceptable in this context? If not, what is an alternative approach? (Section XIX.C)

84. Should EPA use the results of the HWIR model to revise LDR standards? (Section XX.D)

85. Should HWIR exemption levels replace existing technology-based LDR standards, where the exemption levels are less stringent than the current LDR values? (Section XX.E)

86. Are the scope, methodology, assumptions, data sources, and other elements of the Economic Assessment background document for this proposal, adequate for describing and estimating the potential economic effects of HWIR? (Section XXI)

87. Should EPA require HWIR waste to be below 500 ppmw for volatile organics, and, if so, should this cap be applied to waste exempted under the landfill-only HWIR exemption as well? (Section XXII.F)

88. Should EPA in the future revise 40 CFR 266.20 to apply HWIR exemption levels to hazardous waste used in a manner constituting disposal? (Section XXII.G)

89. Should EPA required contaminated media to be tested for a broader list of HWIR exemption chemicals than that required for other wastes? If so, how should this broader list be developed? (Section XXII.I)

List of Subjects in 40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Waste treatment and disposal.

Dated: October 29, 1999.

Carol M. Browner,

Administrator.

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924y, and 6938.

2. Section 261.3 is amended by:

A. Removing paragraph (a)(2)(iii);

B. Redesignating paragraphs (a)(2)(iv) through (a)(2)(v) as paragraphs (a)(2)(iii) through (a)(2)(iv);

C. Revising newly designated paragraph (a)(2)(iii) and the first sentence of paragraph (c)(2)(i); and

D. Adding paragraph (g).

§ 261.3 Definition of hazardous waste.

(a) * * *

(2) * * *

(iii) It is a mixture of solid waste and one or more hazardous wastes listed in subpart D of this part and has not been excluded from paragraph (a)(2) of this section under §§ 260.20 and 260.22 of this chapter, paragraph (g) of this section, or under part 266, subpart N of this chapter; however the following mixtures of solid wastes and hazardous wastes listed in subpart D of this part are not hazardous waste (except by application of paragraph (a)(2)(i) or (ii) of this section) if the generator can demonstrate that the mixture consists of wastewater the discharge of which is subject to regulation under either section 402 or section 307(b) of the Clean Water Act (including wastewater at facilities which have eliminated the discharge of wastewater) and;

* * * * *

(c) * * *

(2) * * *

(i) Except as otherwise provided in paragraph (c)(2)(ii) or (g) of this section or in part 266, subpart N, any solid waste generated from the treatment, storage, or disposal of a hazardous waste, including any sludge, spill residue, ash emission control dust, or leachate (but not including precipitation run-of) is a hazardous waste. * * *

* * * * *

(g)(1) A hazardous waste that is listed in subpart D of this part solely because it exhibits one or more characteristics of ignitability as defined under § 261.21, corrosivity as defined under § 261.22, or reactivity as defined under § 261.23 is excluded from regulation, if the waste no longer exhibits any characteristic of hazardous waste identified in subpart C of this part.

(2) The exclusion described in paragraph (g)(1) of this section also pertains to:

(i) Any mixture of a solid waste and a hazardous waste listed in subpart D of this part solely because it exhibits the characteristics of ignitability, corrosivity, or reactivity as regulated under paragraph (a)(2)(iii) of this section; and,

(ii) Any solid waste generated from treating, storing, or disposing of a hazardous waste listed in subpart D of this part solely because it exhibits the characteristics of ignitability, corrosivity, or reactivity as regulated under paragraph (c)(2)(i) of this section.

(3) Wastes excluded under this section are still subject to part 268 of this chapter, even if they no longer exhibit a characteristic at the point of land disposal.

[FR Doc. 99–29067 Filed 11–18–99; 8:45 am]

BILLING CODE 6560–50–P

Federal Register

Friday
November 19, 1999

Part III

Environmental Protection Agency

40 CFR Part 266

Storage, Treatment, Transportation, and Disposal of Mixed Waste; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 266

[FRN–6470–1]

RIN 2050–AE45

Storage, Treatment, Transportation, and Disposal of Mixed Waste

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; request for comments.

SUMMARY: The Environmental Protection Agency (EPA) is today proposing to provide increased flexibility to facilities that manage low-level mixed waste (LLMW) and naturally occurring and/or accelerator-produced Radioactive Material (NARM) mixed with hazardous waste. The proposal also aims to reduce dual regulation of LLMW, which is subject to Resource Conservation and Recovery Act (RCRA) and to the Atomic Energy Act (AEA). We believe the changes we are proposing will lower cost and reduce paperwork burden, while improving or maintaining protection of human health (including worker exposure to radiation) and the environment.

We are proposing to allow on-site storage and treatment of these wastes at the generator's site. Today's proposal will require the use of tanks/containers to solidify, neutralize, or otherwise stabilize the waste and would apply only to generators of low-level mixed waste who are licensed by the Nuclear Regulatory Commission (NRC) or an Agreement State.

We also seek to exempt LLMW and hazardous NARM waste from RCRA manifest, transportation, and disposal requirements when certain conditions are met. Under this conditional exemption, generators and treaters must still comply with manifest, transport, and disposal requirements under the NRC (or NRC-Agreement State) regulations for LLW or NARM.

DATES: To make sure we consider your comments, they must be received on or before February 17, 2000.

We are seeking comment on this proposed rulemaking from all interested parties.

ADDRESSES: You can send an original and two copies of your comments referencing Docket Number F–99–ML2P–FFFFF to (1) if using regular US Postal Service mail: RCRA Docket Information Center, Office of Solid Waste (5305G), U.S. Environmental Protection Agency Headquarters (EPA, HQ), 401 M Street, SW, Washington, D.C. 20460, or (2) if using special delivery, such as overnight express service: RCRA Docket Information Center (RIC), Crystal Gateway One, 1235 Jefferson Davis Highway, First Floor, Arlington, VA 22202. It would also be helpful, although not mandatory, to include an electronic copy by diskette or Internet E-mail. In this case, send your comments to the RCRA Information Center on labeled personal computer diskettes in ASCII (TEXT) format or a word processing format we can convert to ASCII (TEXT). Please include on the disk label the name and version or edition of your word processing software as well as your name. Protect your diskette by putting it in a protective mailing envelope. To send a copy by Internet E-mail, address it to: rcra-docket@epamail.epa.gov. Make sure this copy is in ASCII format that doesn't use special characters or encryption. Cite the docket Number F–99–ML2P–FFFFF in your electronic file. Commenters should not submit electronically any confidential business information (CBI). An original and two copies of CBI must be submitted under separate cover to: RCRA CBI Document Control Officer, Office of Solid Waste (5305W), U.S. EPA, 401 M Street, SW, Washington, D.C. 20460.

The RCRA Information Center is at Crystal Gateway One, 1235 Jefferson Davis Highway, First Floor, Arlington Virginia. You may look at and copy supporting information for RCRA rules from 9:00 a.m. to 4:00 p.m. Monday through Friday, except for Federal holidays. To review docket materials you should make an appointment by calling (703) 603–9230. You may copy up to 100 pages from any regulatory document at no cost. Additional copies cost $0.15 per page. The index and some supporting materials are available electronically. See the Supplementary Information section for information on accessing them.

FOR FURTHER INFORMATION CONTACT: For general information about this proposed rule, contact the RCRA Hotline, Office of Solid Waste, U.S. Environmental Protection Agency, Washington, D.C. 20460, at (800) 424–9346 (toll free); or TDD (800) 553–7672 (hearing impaired). In the Washington, D.C. metropolitan area call (703) 412–9810 or TDD (703) 486–3323 (hearing impaired). For information on the disposal portion of the proposed rule, contact Grace Ordaz at (703) 308–1130 in the Office of Solid Waste. For information on the storage portion of the proposed rule, contact Nancy Hunt at (703) 308–8762 or Chris Rhyne at (703) 308–8658 in the Office of Solid Waste. To get copies of the reports or other materials referred to in this proposal, contact the RCRA Docket at the phone number or address listed above.

SUPPLEMENTARY INFORMATION: Follow these instructions to access the rule electronically on the Internet: www:http://www.epa.gov/epaoswer/hazwaste/radio.

The official record for this section will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into paper form and place them in the official record, which will also include all comments submitted directly in writing. The official record is the record maintained at the address in **ADDRESSES** at the beginning of this document. Please note, even if you commented on the March 1, 1999 Advance Notice of Proposed Rulemaking (64 FR 10063), for your comments to be considered for the final rulemaking, you must again submit comments on this revised and expanded proposal.

EPA responses to comments, whether the comments are written or electronic, will be in a notice in the **Federal Register** or in a response to comments document placed in the official record for this rulemaking. EPA will not immediately reply to commenters electronically other than to seek clarification of electronic comments that may be garbled in transmission or during conversion to paper form.

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Acronyms Used in This Preamble

AEA—Atomic Energy Act of 1954, as amended
ALRA—As Low As Is Reasonably Achievable
ANPR—Advance Notice of Proposed Rulemaking
ARAR—Applicable or Relevant and Appropriate Requirements
BDAT—Best Demonstrated Available Technology
CBI—Confidential Business Information
CERCLA—Comprehensive Environmental Response, Compensation, and Liability Act
DOD—Department of Defense
DOE—Department of Energy
EEI—Edison Electric Institute
EPA—Environmental Protection Agency (referred to as ''we'' throughout this document)
FFCA—Federal Facilities Compliance Act
FUSRAP—Formerly Utilized Sites Remedial Action Program
GWRL—Groundwater risk levels
HSWA—Hazardous and Solid Waste Amendments of 1984
HWIR—Hazardous Waste Identification Rule
ICR—Information Collection Request
LDR—Land Disposal Restrictions
LLW—Low-Level Radioactive Waste
LLMW—Low-Level Mixed Waste
LLRWDF—Low-Level Radioactive Waste Disposal Facility
MMR—Military Munitions Rule
NAAG—National Association of Attorneys General
NARM—Naturally Occurring and/or Accelerator-produced Radioactive Material
NGA—National Governors' Association
NNPP—Naval Nuclear Propulsion Program
NRC—Nuclear Regulatory Commission
NTTAA—National Technology Transfer and Advancement Act
OMB—Office of Management and Budget
OSW—Office of Solid Waste
RCRA—Resource Conservation and Recovery Act
RFA—Regulatory Fairness Act
RIC—RCRA Information Center
RQ—Reportable Quantity
SARA—Superfund Amendments and Reauthorization Act
SBREFA—Small Business Regulation Enforcement Fairness Act
SQG—Small Quantity Generator
TC—Toxicity Characteristic
TRI—Toxics Release Inventory
TSDF—Treatment, Storage and Disposal Facility
UHC—Underlying Hazardous Constituent
UMRA—Unfunded Mandates Reform Act of 1995
UMTRCA—Uranium Mill Tailings Radiation Control Act
USWAG—Utility Solid Waste Activities Group
UTS—Universal Treatment Standards

Definition of Terms Used in the Preamble

Agreement State—means a state that has entered into an agreement with the NRC under subsection 274b of the Atomic Energy Act of 1954, as amended (68 Stat. 919), to assume responsibility for regulating within its borders source, special nuclear, or byproduct material

in quantities not sufficient to form a critical mass.

ANPR (Advance Notice of Proposed Rulemaking)—refers in this document to the advance notice published in the **Federal Register** on March 1, 1999 (64 FR 10063) on mixed waste storage.

Appropriately trained—means trained in a manner that ensures that low-level mixed waste is safely managed and includes training in chemical and radiological waste management.

Eligible NARM—for the purpose of this proposal, means NARM that meets the acceptance criteria of a LLRWDF licensed by NRC or an Agreement State in accordance with 10 CFR 61, and is also contaminated by a hazardous waste, and therefore, is eligible for the transportation and disposal conditional exemption.

Hazardous waste—means any material which is defined to be hazardous waste in accordance with 40 CFR 261.3, ''Definition of Hazardous Waste.''

Legacy waste—means waste that was generated by past activities and is in storage because appropriate treatment technologies have not been developed, or treatment and disposal capacity has not been available. It has been stored longer than RCRA regulatory time limits.

Low-Level Mixed Waste (LLMW)—means low-level radioactive waste containing a RCRA hazardous waste component.

Low-Level radioactive waste (LLW)—means radioactive waste containing source, special nuclear, or by-product material which is not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, byproduct material as defined in § 11(e)(2) of the Atomic Energy Act or NARM. (See also NRC definition of ''waste'' at 10 CFR 61.2)

Low-Level Radioactive Waste Disposal Facility (LLRWDF)—means a disposal facility licensed by the NRC or Agreement State for the disposal of low-level waste.

Mixed Waste—defined in RCRA as amended by the Federal Facility Compliance Act of 1992, means a waste that contains both RCRA hazardous waste and source, special nuclear, or by-product material subject to the Atomic Energy Act of 1954, as amended.

Mixed Waste Treatment Facility—means a waste treatment facility permitted by EPA or an Authorized State to treat hazardous waste and licensed by the NRC or Agreement State to manage radioactive waste.

Naturally Occurring and/or Accelerator-produced Radioactive Material (NARM)—means radioactive materials that are naturally occurring or produced by an accelerator. The naturally occurring radioactive material (NORM) is defined below. Currently NARM is not regulated by NRC or EPA. Rather it is regulated by the States under State law, or by DOE under DOE Orders.

Naturally Occurring Radioactive Material (NORM)—is a subset of NARM and refers to materials whose radioactivity has been enhanced (radionuclide concentrations are either increased or redistributed where they are more likely to cause human exposures) usually by mineral extraction or processing activities. Examples are exploration and production wastes from the oil and natural gas industry, and phosphate slag piles from the phosphate mining industry. This term is not used to describe or discuss the natural radioactivity of rocks and soils, or background radiation, but instead refers to materials whose radioactivity is technologically enhanced by controllable practices.

NRC or Agreement State license—means a license issued by the Nuclear Regulatory Commission or an Agreement State under authority granted by the AEA.

NUREG—refers to Nuclear Regulatory Commission publications and documents that include: formal staff reports, which cover a variety of regulatory, technical and administrative subjects; brochures, which include manuals, procedural guidance, directories and newsletters; conference proceedings and papers presented at a conference or workshop; and books, which serve a technical purpose or an industry-wide needs. Many of the NUREG documents are listed on the NRC Home Page (*http://www.nrc.gov*).

On-site—is defined in the RCRA regulations at 40 CFR 260.10, *et seq.*

RCRA program agency—means EPA, or the State agency authorized to implement the RCRA program.

Radioactive waste—is generally classified as source, special nuclear, or by-product material, and is exempt from the definition of solid waste at 42 U.S.C. 6903, 40 CFR 261.4(a)(4).

Tie-down conditions—include NRC guidance documents and policies concerning storage and treatment of LLW which become part of the NRC or Agreement State radioactive materials license by reference.

Who is Eligible for This Rule?

The conditional exemption proposed for low-level mixed waste (LLMW) storage and treatment applies to any mixed waste generator that has an NRC or Agreement State license to possess radioactive material or to operate a nuclear reactor, so long as the waste generator can satisfy the conditions set forth in this proposal.

The transportation and disposal exemption applies to generators of LLMW and eligible NARM so long as they meet all specified conditions. Facilities potentially affected by this action include those identified in Table 1.

TABLE 1.—FACILITIES POTENTIALLY AFFECTED BY THE PROPOSAL

Category	Examples of regulated facilities
Nuclear Utilities	Firms that generate electricity using nuclear fuel as the source of energy and have been licensed by the NRC
Universities and Academic Institutions.	Academic institutions at all levels that are licensed by NRC, or an Agreement State, to use radionuclides for academic, biomedical, and research purposes.
Medical Facilities	Hospitals, medical laboratories, doctors' offices, or clinics that are licensed by NRC or an Agreement State to use radionuclides for health care purposes
Industrial Establishments	Private companies and institutions, including pharmaceutical companies, and research and development institutions
Governmental Facilities	Facilities, installations and laboratories operated by State Agencies, and by Federal Agencies, including, but not limited to, DOE (including the Naval Nuclear Propulsion Program), the National Institutes of Health, the National Institute of Standards and Technology, and the Department of Defense.

The preceding table is not intended to be exhaustive, but rather provides examples of facilities likely to be affected by this proposal. To determine whether you are affected by this regulatory action, you should carefully

examine the applicability criteria in Parts V and VI of this preamble. If you have any questions regarding the applicability of this section to a particular entity, consult the persons listed under **FOR FURTHER INFORMATION CONTACT**.

I. Statutory Authority

The statutory basis for this rule is in Sections 2002(a), 3001, 3002, 3004, 3005, 3006, 3007, and 3013 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA) and the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924, 6926, 6927 and 6934.

II. Summary of Today's Action

In today's notice we are proposing a conditional exemption for the storage, treatment, transportation, and disposal of low-level mixed waste (LLMW) pursuant to the Hazardous Waste Identification Rule (HWIR) consent decree (see II. B.) regarding potential regulatory flexibility related to hazardous waste disposal requirements and other relief as appropriate for commercial mixed waste. (See Ref. 1, Consent Decree and Ref. 2, Side-bar Letter.) As an NRC-licensed generator who meets certain conditions we specify, (a) your LLMW would be exempt from some RCRA Subtitle C storage and treatment regulations, and (b) your LLMW and eligible NARM (see definitions and discussion in VI. B. 1.), would be exempt from some RCRA Subtitle C manifesting, transportation, and disposal regulations. However, your LLMW and eligible NARM waste remain subject to RCRA land disposal restriction (LDR) treatment standards under the transportation and disposal exemption.

The ''Diagram of the Storage, Treatment and Disposal Exemptions Under the Proposal'' gives an overview of when waste would be conditionally exempt from certain RCRA hazardous waste management requirements. Briefly, LLMW generated and stored onsite in tanks or containers is exempted as long as the exemption conditions listed in § 266.230 are met. NRC or Agreement State-licensed generators may treat their LLMW on-site pursuant to the limitations imposed by § 266.235. Any generator may send LLMW and eligible NARM waste for disposal to a low-level radioactive waste disposal facility (LLRWDF) licensed by the NRC or an Agreement State, if all the conditions are met. Thus, certain LLMW and eligible NARM waste of NRC licensees may remain exempted from many RCRA requirements through much of the waste management process.

If your LLMW and eligible NARM is not treated to meet LDR treatment standards and is sent off-site for storage, treatment or disposal, your waste remains subject to all RCRA Subtitle C and NRC management requirements. LLMW treated off-site at mixed waste treatment facilities to meet LDR treatment standards may be eligible for the disposal exemption if all conditions for the transportation and disposal exemption are met.

In order to claim a conditional exemption for storage or disposal you must notify the RCRA program agency that you meet the conditions. However, if information you provide on your notification is inaccurate, your claim for a conditional exemption is nullified and you will be subject to RCRA Subtitle C enforcement.

A. What Regulatory Changes are We Proposing for On-Site Storage and Treatment of LLMW?

Our proposal would allow generators of LLMW to claim a conditional exemption from the RCRA definition of hazardous waste for mixed wastes stored on-site (40 CFR 260.10). This conditional exemption acknowledges the protectiveness of storage of mixed waste subject to NRC regulations for low-level waste (LLW). During the storage of LLMW, our proposal would allow the conditionally exempt waste to be treated in tanks or containers to enable neutralization, solidification, or other stabilization of the hazardous portion of the waste. This regulatory flexibility would apply only to generators of low-level mixed waste who are licensed by NRC. Once your LLMW is removed from storage for further management, it is subject to hazardous waste management requirements unless it qualifies for a disposal exemption. In that case, you must show that it: meets the RCRA LDR treatment standards and NRC's LLW disposal requirements; and is destined for disposal at LLRWDFs licensed by NRC.

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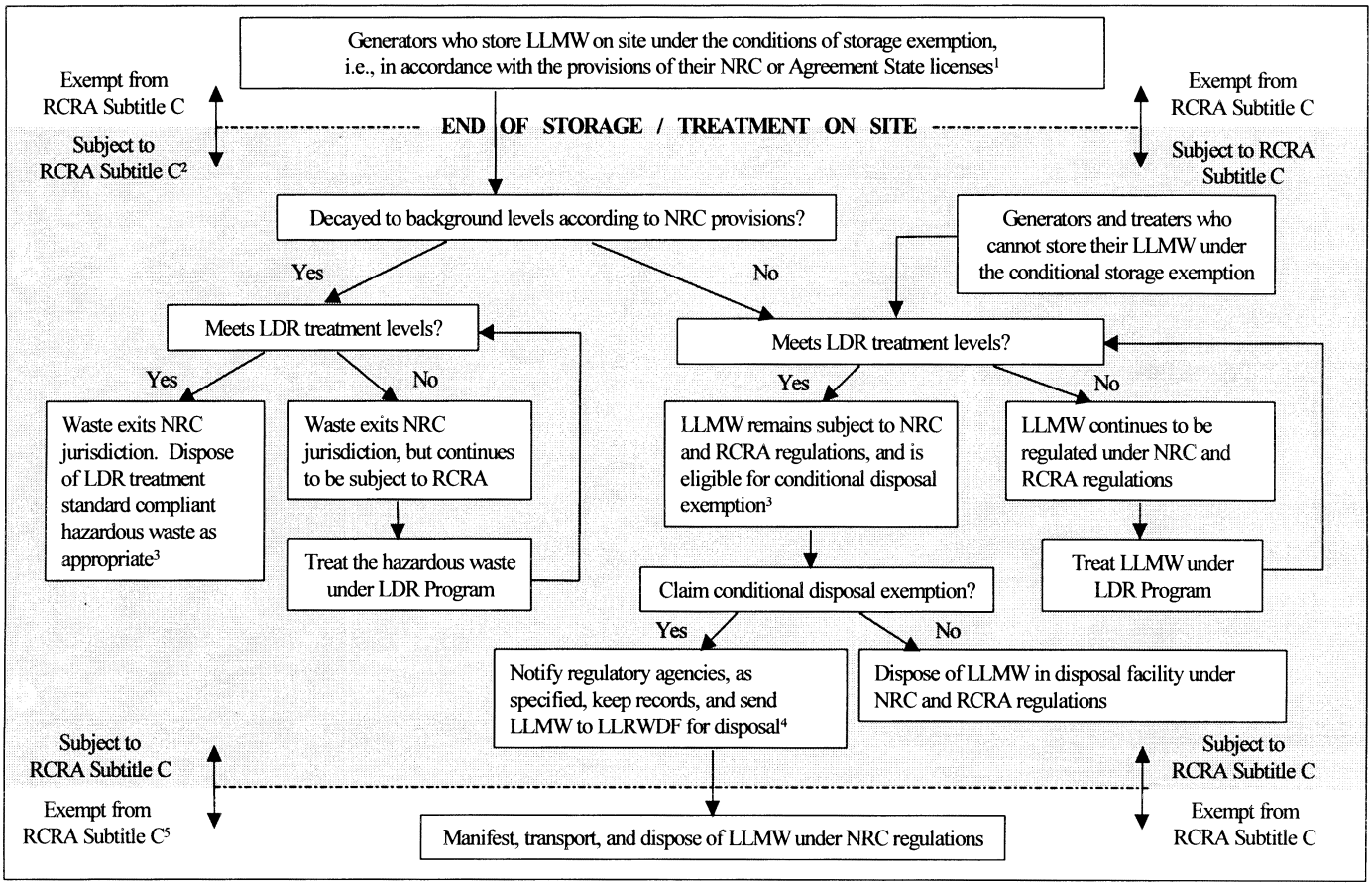
Diagram of the Storage, Treatment, and Disposal Exemptions Under the Proposal



[1] All licensees (whether NRC or Agreement State) generating LLMW may be eligible for the storage exemption; however, as long as specified applicable conditions are met. Non-licensed entities (e.g., DOE) and commercial treatment, storage, and disposal facilities are not eligible for the storage exemption. They may be eligible for the disposal exemption. Diagram assumes licensees meet all conditions (and administrative requirements) for storing their LLMW under the conditional exemption for storage. LLMW under the storage exemption may be treated (e.g., stabilized), consistent with the generator's NRC or Agreement State license.

[2] Waste becomes subject to RCRA Subtitle C after storage ends (e.g., generator standards at 40 CFR Part 262), as indicated in this diagram.

[3] Ignitable, corrosive, and reactive hazardous wastes exit RCRA Subtitle C when LDR standards are met.

[4] LLMW disposal is restricted to low-level radioactive waste disposal facility (LLRWDF) licensed by the NRC or Agreement State.

[5] LLMW exits RCRA Subtitle C when it is en route to a LLRWDF for disposal.

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B. What Regulatory Changes Are We Proposing for Transportation and Disposal of LLMW and Eligible NARM?

We are proposing a conditional exemption from hazardous waste transportation, and disposal requirements for LLMW, and for eligible NARM. (See discussion in VI.B.1.) (Throughout this document when we refer to the conditional exemption for transportation and disposal of LLMW, we also mean eligible NARM.) The transportation and disposal exemption would not take effect until you fulfill all of the following conditions: (1) Treat your waste to meet the RCRA LDR treatment standards; (2) notify appropriate regulatory agencies of your exemption claim; (3) ship your waste according to NRC and DOT shipping requirements for transportation of LLW using an NRC Uniform LLW Manifest (Form 540, 541, and 542) for immediate disposal to a facility licensed by the NRC or an Agreement State; and (4) maintain appropriate records (including LDR records) for required time periods. Meeting all the prescribed conditions will allow your LLMW or NARM-contaminated hazardous waste to be exempt from the RCRA regulatory definition of hazardous waste.

Under this exemption, you may not send your conditionally-exempt LLMW or eligible NARM for disposal to a DOE radioactive waste disposal facility. Such action would make your waste subject to RCRA hazardous waste regulation, and potentially subject you to RCRA enforcement authority. Note that DOE LLMW which meets the conditions of the exemption for disposal may be shipped to an NRC-licensed disposal facility.

III. Why Are We Proposing a Storage, Treatment, Transportation, and Disposal Rulemaking?

Mixed waste is regulated under multiple authorities: RCRA (for the hazardous component), as implemented by EPA or Authorized States; and AEA (for the source, special nuclear, or byproduct material component), as implemented by the NRC or NRC or an Agreement State (for commercially-generated mixed wastes), or the Department of Energy (DOE) (for defense-related mixed waste generated by DOE activities. NARM-contaminated hazardous waste is also regulated under multiple authorities: RCRA (for the

hazardous component); and State law (for the NARM component), as implemented by a State agency designated by State law. We are proposing to make RCRA Subtitle C regulations more flexible so that generators of LLMW and eligible NARM are relieved of some dual regulatory requirements in managing their mixed wastes.

A. Need To Address Dual Regulation Concerns

Members of the regulated community have informed us that the combination of RCRA and NRC requirements for LLMW is burdensome, duplicative, and costly and does not provide more protection of human health and the environment than that achieved under one regulatory regime. We are responding to these concerns about the inefficiencies of dual regulation, as well as concerns about the radiation exposure of workers.

In addition, other mixed waste generators have expressed concerns about limited capacity of LLMW treatment and disposal. These concerns originated because RCRA § 3004(j) generally prohibits the storage of hazardous wastes that are also subject to RCRA land disposal restrictions unless the storage is ''solely for the purpose of the accumulation of such quantities of hazardous waste as are necessary to facilitate proper recovery, treatment or disposal.'' Under EPA's regulation codifying RCRA § 3004(j) we presume that the initial year of hazardous waste storage is for the sole purpose of accumulating a quantity necessary to facilitate treatment and disposal. However, if you store LLMW on-site for more than one year, you have the burden of proving that the storage is for the allowed purpose.

Based on our information collection effort in the ANPR and information from mixed waste generators, we found that capacity for the treatment and disposal of certain LLMW is not always available (that is, LLMW containing certain radionuclides are not allowed to be disposed at the *only* LLMW disposal unit—licensed by the State of Utah, an NRC Agreement State). We also found that commercial mixed waste treatment facilities have not been willing to accept LLMW for treatment without viable disposal options. Since mixed waste disposal capacity is lacking, some generators of LLMW store the waste on-site. In addition, we found that the possibility of siting a new LLMW disposal facility is extremely low. Because of the very limited LLMW disposal capacity and the low probability of a disposal facility being built in the near future, we believe it is appropriate to provide safe and legal alternatives for the disposal of LLMW. We also believe that the availability of alternate disposal capacity would enable disposal of ''legacy'' wastes currently in on-site storage by generators of LLMW.

We have assessed NRC regulations for storage and disposal of LLW and compared them with EPA's regulations for hazardous waste storage, treatment, transportation, and disposal. Our review suggests that given the NRC's regulatory controls, human health and environmental protection from chemical risks would not be compromised if we deferred to NRC LLW management practices. Through this action, we are proposing regulatory relief intended to allow the disposal of certain LLMW (such as legacy waste requiring long-term storage due to lack of treatment and disposal capacity), that have, until now, been stored on-site by NRC licensees as mixed waste subject to both RCRA permitting and NRC licensing requirements.

A similar situation exists at DOE facilities. Available information suggests that currently DOE cannot treat some of its LLMW due to a lack of treatment capacity. DOE operations, therefore, must store their LLMW pursuant to a RCRA storage permit. However, DOE is also subject to state compliance orders and other requirements for treatment of its mixed waste as a result of the Federal Facility Compliance Act of 1992 (FFCA, P.L. 102–386, October 6, 1992). This rulemaking effort may result in removal of some DOE ''legacy'' waste from storage if DOE: increases its own mixed waste treatment capacity or uses commercial mixed waste treatment capacity to meet land disposal treatment standards; and disposes of LLMW treated to LDR treatment standards in a LLRWDF licensed by NRC by meeting the conditions specified to qualify for an exemption from disposal of LLMW as a RCRA hazardous waste.

We seek comment on the ways we propose to address the issue of dual regulation of LLMW storage, treatment, transportation, and disposal.

B. Need To Respond to HWIR Consent Decree

The Edison Electric Institute (EEI), the Utility Solid Waste Activities Group (USWAG), and the Nuclear Energy Institute (NEI)—trade groups representing commercial nuclear power plants—were parties to settlement discussions regarding the deadline for the final Hazardous Waste Identification Rulemaking, *ETC* v. *Browner*, C.A. No. 94–2119 (TFH) (D.D.C.). On April 11, 1997, the court entered a consent decree which requires EPA to propose revisions to the mixture and derived-from rules, 40 CFR 261.3(a)(2)(iv) and (c)(2)(I) and to seek comment on eleven items listed in the decree with respect to those revisions. One of the eleven items concerns an exemption from RCRA hazardous waste disposal regulations for nuclear power plant low-level mixed waste. The proposal must also request comment on other regulatory relief for these wastes, if EPA finds that any other relief would be appropriate. (See ANPR for further information.)

Today's notice requests comment on EPA's proposal to provide regulatory relief to LLMW generators and other regulatory relief as described in this document. In a separate notice (see Docket # F–99–WH2P–FFFFF), EPA is proposing revisions to the mixture and derived-from rules and requesting comment on the other ten items set forth in the consent decree. Those proposed revisions include an exemption for mixed waste that is managed in compliance with the requirements in part 266, subpart N proposed here today.

C. Need To Respond to a Rulemaking Petition From USWAG and Concerns of Other Mixed Waste Generators Regarding Capacity

The Utility Solid Waste Activities Group (USWAG), a national organization of power companies, petitioned the U.S. EPA on January 13, 1992 to request an amendment to RCRA Subtitle C regulations governing storage of mixed wastes. The USWAG organization cited difficulties in complying with RCRA Subtitle C regulations because of limited treatment technology and disposal capacity for some mixed wastes. (See discussion in ANPR for additional information.) We regard today's action as a response to the USWAG petition.

Policy of Lower Enforcement Priority for Mixed Waste

Recognizing this capacity difficulty, we issued a policy on the lower priority of enforcement of the storage prohibition contained in § 3004(j) of RCRA. (See 56 FR 42730; August 29, 1991) § 3004(j) prohibits storage of a land disposal restricted waste (including mixed waste), except for the purposes of the accumulation of such quantities of hazardous waste necessary to facilitate proper recovery, treatment, or disposal. Because treatment technology or disposal capacity was still unavailable for some mixed wastes, we extended this policy on October 31,

1998. The lack of adequate treatment technology or disposal capacity for some mixed waste streams necessitated storage in violation of land disposal restrictions for storage of mixed waste. The policy stated that violators who: were faced with the impossibility of complying with the RCRA regulations; had a RCRA storage permit; and were storing their wastes in an environmentally responsible manner would be a low enforcement priority for EPA. The extension of the policy expires October 31, 2001. (See 63 FR 59989; November 6, 1998.) This proposed rulemaking is expected to replace the current enforcement policy.

IV. Precedent for Regulatory Flexibility in This Proposal

We are proposing regulatory flexibility modeled on the conditional exemption developed for waste military munitions in the Military Munitions Rule (40 CFR part 266, Subpart M) published February 12, 1997 (62 FR 6622–6657).

A. How Does the Conditional Exemption in the Military Munitions Rule Work?

The Military Munitions Rule (MMR) identifies when conventional and chemical military munitions become a hazardous waste subject to RCRA Subtitle C. In the MMR, EPA developed a conditional exemption to provide regulatory flexibility to storers and transporters of non-chemical waste military munitions. Under the conditional exemption, non-chemical waste military munitions that normally meet the definition of ''hazardous waste'' are not regulated under RCRA Subtitle C as a hazardous waste so long as the facilities storing or transporting munitions meet all of the conditions for storing and transporting non-chemical waste munitions listed in the rule. (For the complete text of the Military Munitions Rule, see 62 FR 6621, February 12, 1997.)

The Court of Appeals upheld all aspects of the MMR in *Military Toxics Project* v. *EPA*, 146 F. 3rd 948 (D.C. Cir. 1998). The court agreed that ''Congress has not spoken directly to the issue of conditional exemption,'' and upheld as reasonable EPA's interpretation that § 3001(a), which requires the Administrator to promulgate criteria for identifying and listing wastes that should be subject to Subtitle C requirements, allows the use of conditional exemptions. (Ibid.) The court also agreed with EPA that ''where a waste might pose a hazard only under limited management scenarios, and other regulatory programs already address such scenarios, EPA is not required to classify a waste as hazardous waste subject to regulation under Subtitle C.'' (Ibid. at 958.)

B. What Is Our Rationale for Today's Proposed Conditional Exemption?

In the MMR, EPA conditionally exempted stored waste military munitions and transported from one military owned or operated facility to another. However, waste military munitions treatment, and disposal remain subject to RCRA Subtitle C. We take a comparable approach for generators of LLMW in this proposed rulemaking in that we propose to provide a conditional exemption for the storage, treatment, transportation, and disposal of LLMW that is also subject to NRC or Agreement State regulation. We base this proposal on the NRC or the NRC Agreement State licensing process and regulatory requirements, and their adequacy in addressing risks from radioactivity and RCRA hazardous constituents. By promulgating a conditional exemption, we can eliminate redundant or dual requirements where wastes are managed safely and mismanagement is unlikely; the NRC-required safeguards are in place (for example, inspection, monitoring, record keeping, reporting); and penalties or other consequences may be imposed if the governing regulatory framework is not followed.

In proposing a conditional exemption from RCRA Subtitle C regulation for storage/treatment of NRC-licensee generated LLMW, we evaluated certain key factors. First, we reviewed the licensing requirements and NRC standards for the storage and treatment of LLW to determine whether NRC regulation of stored low-level waste (LLW) adequately protects against possible risks from RCRA hazardous constituents in mixed waste. Although NRC regulation and oversight are designed primarily for radiation risks, the NRC, the regulated industry, and others have argued that these standards largely duplicate RCRA requirements and thus, protect against chemical risks to human health and the environment. Second, we compared NRC low-level waste and EPA hazardous waste storage and treatment requirements. (See Ref. 4, EPA's comparison of storage and treatment requirements, for details.) Our analysis was done independently of similar studies performed by USWAG, the Electric Power Research Institute, and the Nuclear Management and Resources Council, Inc. (who represent members of the power generation industry) regarding applicable NRC standards. (See Ref. 6 and 16 for the industry studies.) These other studies concluded that the technical design and operating standards of the NRC meet or exceed RCRA standards in virtually all respects, though there were differences noted in emphasis (performance based rather than proscriptive requirements) and implementation of NRC licensing requirements. Third, we reviewed the compliance history of licensed facilities. We looked at the documentation of incidents involving the storage and on-site treatment of radioactive wastes by LLMW generators who are NRC licensed users of radionuclides. Our review of documented information suggests that NRC licensed facilities almost universally have good low-level waste management safety records. (See Ref. 3, EPA's compliance record review.) Based on our evaluation of these factors, we concluded that low-level mixed wastes stored and treated at these facilities are not likely to be mismanaged, and that regulation under RCRA Subtitle C does not increase protection to human health and the environment for these wastes during on-site storage and treatment.

In addition to storage and treatment requirements, we reviewed NRC requirements and the practices of low-level waste disposal facilities to determine if they provide human health and environmental protection similar to that achieved upon the disposal of low-level mixed waste at RCRA Subtitle C disposal facilities. (Ref. 7, Technical assessment of LLRWDFs) Our review suggests that NRC regulations for disposal facilities provide adequate protection so long as the hazardous constituents are treated to LDR treatment standards prior to disposal. Therefore, compliance with LDR treatment standards is required to obtain the conditional exemption for disposal of LLMW or eligible NARM. Disposal facilities licensed by the NRC will be accepting for disposal conditionally-exempt LLMW as a low-level waste. We believe that LLMW or eligible NARM disposed at these facilities are not likely to be mismanaged and, therefore, RCRA Subtitle C regulation is not necessary to protect human health and the environment.

V. Low-Level Mixed Waste Storage and Treatment

We are proposing a conditional exemption from RCRA Subtitle C requirements to provide regulatory flexibility related to storage and treatment for (1) the on-site storage of low-level mixed waste if specified conditions are met; and (2) the on-site treatment of low-level mixed waste in qualified tanks or containers (40 CFR 262.34). This regulatory flexibility applies to any generator of LLMW who

is an NRC licensee licensed to manage radioactive materials.

A. What Conditional Exemption for Stored or Treated Low-Level Mixed Waste Are We Proposing?

We are proposing in today's action to conditionally exempt LLMW from the regulatory definition of hazardous waste, found in § 261.3, while the waste is stored and/or treated on-site. The conditional exemption is available only to NRC licensees who generate LLMW. Generators must notify EPA of the storage units for which they are claiming an exemption and meet other conditions listed below. During storage or treatment of conditionally exempted LLMW, the generator will not be required to have a RCRA storage permit for the conditionally exempt waste. The conditional exemption proposed today applies only to LLMW and does not affect other RCRA wastes a licensee may generate. A RCRA permit may be required for management of those other wastes depending on the circumstances. This proposal also describes which wastes are eligible for the conditional exemption (§ 266.225), what a generator must do to qualify for the exemption if specified conditions are met (§ 266.230), and how the exemption will be implemented (§ 266.240 and following).

Under our proposal if you fail to meet any of the conditions, your LLMW is no longer exempted from the definition of hazardous waste. As a hazardous waste, your LLMW would be subject to RCRA Subtitle C regulation. Also, if a release or other incident of waste spill occurs while the waste is being stored, your waste may be subject to regulation as a hazardous waste. For example, you may be subject to the provisions of RCRA § 7003 which specify that in any situation where an imminent and substantial endangerment to health or the environment is caused by the handling of solid or hazardous wastes EPA can order any person contributing to the problem to take steps to clean it up. Violation of RCRA § 7003 orders can result in significant penalties.

1. How Does the Proposal Facilitate Decay-in-Storage?

NRC generally allows research, medical, and other facilities to store low-level wastes containing radionuclides with half-lives of less than 65 days (or more under an amended license) until 10 half-lives have elapsed and the radiation emitted from the unshielded surface of the waste (as measured with an appropriate survey instrument) is indistinguishable from background levels. This process is known as decay-in-storage. Our proposal facilitates decay-in-storage by supporting NRC license provisions related to short-lived radionuclides, and NRC requirements to limit worker exposures to meet ALARA (as low as reasonably achievable). Once the specified radionuclide decay has occurred, the waste may then be disposed of as non-radioactive waste after ensuring that all radioactive material labels are rendered unrecognizable (see 10 CFR 35.92 and 10 CFR 20.2001).

The time frame for LLW decay-in-storage is based on the radionuclides (and half-lives) specified in a low-level waste generator's NRC license. Such management of LLW significantly reduces worker exposures to radionuclides since containerized wastes are not shipped for treatment and disposal while the short-lived radionuclides are held in storage on-site for the purpose of radioactive decay. This outcome is consistent with the proposed RCRA conditional exemption.

Several universities and medical facilities have indicated to us that a conditional exemption during the decay-in-storage time period would be a way of reducing risk, exposures, and regulatory inefficiency in the management of their LLMW. Commenters on the ANPR confirmed this information. We are proposing that the management of LLMW during on-site storage be regulated under NRC's decay-in-storage requirements.

We anticipate that the requirements will provide regulatory flexibility to academic, medical, research, and other facilities by reducing overlapping RCRA and AEA requirements. For LLMW containing short-lived radionuclides, today's proposed conditional exemption would be temporary because it would be in effect only until the radioactive component of the mixed waste has decayed to a point that it is no longer subject to NRC license requirements. After the decay-in-storage process is completed, the waste becomes subject to RCRA Subtitle C requirements. We would appreciate comments regarding the standard to use for determining when the decayed waste would reenter RCRA Subtitle C management.

2. For What Time Period is a Storage Exemption Valid?

We are proposing that an exemption will be valid as long as the mixed waste: (1) Remains on-site and (2) is subject to NRC regulation. We are considering whether a general storage exemption time limit should be imposed. A time limit may affect both facilities with untreatable legacy wastes and future treatment and disposal capacity. We invite comment on whether a time limit may be appropriate, and, if so, on what basis that time limit might be established.

Under a decay-in-storage scenario, LLMW is no longer subject to NRC regulations when the radioactive portion of the waste can be disposed of as non-radioactive material in accordance with the generator's NRC license. At that point the mixed waste would not be conditionally exempt from RCRA Subtitle C. If the decayed waste still exhibits a RCRA hazardous waste characteristic or is a listed hazardous waste, then it must be shipped promptly off-site for treatment to meet LDR treatment standards, if needed, and disposed at a RCRA Subtitle C facility. Thus, the RCRA storage limit for a formerly mixed, now solely hazardous, waste prior to shipment off-site for treatment and/or disposal begins when: (1) The radionuclide with the longest half-life in a container has decayed as specified in the license (generally ten half-lives but sometimes fewer half-lives); and (2) the radiation emitted from the unshielded surface of the waste is not above background levels as measured by appropriate monitoring equipment as specified by NRC.

Some radionuclides take longer than 10 half-lives to decay to levels that are indistinguishable from background. If we limited the time for decay to either ten half-lives or when the waste no longer registers above background levels, then some portion of LLMW that is being stored may still emit radiation levels above background. To minimize radiation exposures we have used ''and'' in the paragraph above to ensure that the LLMW does not emit radiation that is above background levels as measured by appropriate monitoring equipment. [1] We invite comment on how waste being stored for decay under 10 CFR 20.2001(a)(2) and 10 CFR part 35 can be completely decayed while at the same time reenter RCRA Subtitle C without a gap in time during which the waste is not regulated as either hazardous or radioactive. Please indicate in your comment what mixed wastes you generate that have radionuclides with activity levels which would not qualify for the conditional exemption we are proposing if it were based on whichever occurred first—ten half-lives of decay or not registering above background levels.

[1] Note: The NRC licensee is not required to immediately monitor the waste after decay of 10 half-lives. Prior to monitoring there may be an interval when the waste is hazardous only. However, the lower cost of diposing of hazardous rather than LLMW should serve to encourage prompt monitoring and disposal.

Also indicate how this limitation would affect your management of the waste.

3. What Are Your On-Site Treatment Options?

We are proposing to allow the on-site treatment of LLMW during a storage exemption from hazardous waste regulation under the conditions listed above for the storage conditional exemption. In addition, the mixed waste must be: (a) treated on-site; and (b) physically or chemically treated in a tank or container in accordance with the generator's NRC license requirements. If these conditions are met, then a RCRA treatment permit during storage will not be required.

RCRA allows accumulation and treatment of hazardous waste in a tank or container within 90–270 days of generation of the waste without a permit provided generators comply with the standards for storage tanks and containers. An NRC license may allow solidification, neutralization, or other stabilization of LLW in the tank or container. If the waste also includes RCRA characteristic or listed hazardous material, then a RCRA permit is normally required if the waste is not treated within 40 CFR part 262 accumulation time limits. In this proposal, we are not requiring a RCRA treatment permit from a generator if the on-site treatment is allowed for LLW under the facility's NRC license. Such treatment may, for example, allow cement to be added to a legacy waste (see definitions at the beginning of this proposal) stored in a container such that it will then be able to meet LDR requirements. Or a mixed waste may be treated chemically to neutralize its corrosivity so that it may be safely stored in a tank or container.

EPA's regulations governing on-site storage and treatment in tanks and containers are generally the same as NRC's. Without the proposed conditional exemption, treatment of legacy waste would require a generator to obtain a permit to address an expired RCRA Part 262 accumulation time limit. We are proposing to allow the types of treatment included in NRC licenses to manage the radioactive material in the waste. We believe that additional RCRA requirements would not increase protection of human health and the environment. Nevertheless, more specific controls are appropriate for some forms of treatment, such as thermal treatment (as defined in 40 CFR 260.10) or incineration, because of the complexity of the treatment and the specificity of RCRA requirements. (Thermal treatment is not now allowed under RCRA without a permit even if done within 90 days of generation.) For that reason, under the conditional exemption for on-site storage of LLMW, we are not including on-site thermal treatment of LLMW by generators without an appropriate RCRA permit.

B. What is Our Low-Level Mixed Waste Storage and Treatment Proposal?

We describe our proposal in the following sections which cover what generators and wastes are eligible, what conditions must be met, and how an exemption is claimed.

3. Which Generators and Wastes Will be Eligible for the Storage and Treatment Exemption?

Generators of LLMW regulated by the NRC will be eligible for the proposed storage exemption. The types of facilities that may be affected include nuclear power plants, fuel cycle facilities, pharmaceutical companies, medical and research laboratories, universities and academic institutions, hospitals, and some industrial facilities. We describe eligible wastes in § 266.225 of this proposal.

4. What Conditions Must You Meet as a Generator?

Conditions in § 266.230 which you, as a generator, must meet to qualify for the exemption include the following:

(a) You must have a valid NRC license. Our proposed exemption is predicated on our finding that NRC oversight provides the regulatory control necessary to ensure that the hazardous portion of an exempted waste will not be mismanaged. It is the NRC license, issued and enforced by an independent government agency, that is the basis of the proposed exemption.

(b) You must comply with the requirements of your NRC license for storing low-level mixed waste. We believe that adherence to NRC licensing conditions is important to the safe storage of the hazardous portion of the LLMW stream. As a result of comments we received on the ANPR, we are now requesting comment on whether we should increase the specificity of this condition by limiting it to the kinds of NRC requirements that if violated may result in endangerment of human health or the environment. For example, we could include violation of those terms and conditions that result in filing a report under 10 CFR Subpart M, Section 20.2201–2203. We seek comment on whether this condition should be: broad (and include the loss of the exemption if any LLW storage requirement of the NRC license is not met); or more specific (and limit the loss of the exemption to those violations which may result in an environmental impact).

(c) You must comply with § 266.225 which requires that the eligible waste be subject to regulation by the NRC. The proposal also requires that the waste be generated ''on-site'' at the facility seeking the exemption. (See 40 CFR 260.10 f.) For the purposes of this conditional exemption, we consider your mixed waste to be on-site if you can move your waste without a RCRA manifest from a storage unit at the point of generation to another storage/accumulation area which you own or operate (with the same RCRA ID number). For example, a LLMW generator may transfer waste from one location to another storage location so long as both the locations are owned by the same entity such as a university, or pharmaceutical firm, and are operated under the same RCRA ID number or same NRC license. Thus, under our proposal, commercial mixed waste processing facilities will not be eligible for this exemption for wastes received from their customers. Finally, the proposal requires that the waste be compatibly stored in tanks, or containers. We do not believe other storage units (for example, surface impoundment units) are appropriate storage devices under this proposal. Commenters on the ANPR suggested we extend the conditional exemption to wastes stored ''off-site.'' We request comment regarding both the definition of ''on-site'' and the appropriateness of extending a conditional exemption to facilities that own/operate storage units that do not meet our current definition of ''on-site.'' This conditional exemption applies only to stored waste which is generated and owned by the same facility. We also seek comment on whether the conditional exemption should include a storage facility which serves as a consolidation point for a single entity. For example, a university storage facility that serves several noncontiguous laboratories on a campus which have the same NRC license, or which have the same RCRA hazardous waste generator identification number.

(d) You must notify us (the EPA Region or the RCRA Subtitle C Authorized State Agency) by certified mail, return receipt requested, that you claim the exemption for a storage unit containing low-level mixed waste. Your notification must be signed by the owner, operator, or other appropriate official of your facility. Notification of your claim should be made either within 90 days of the effective date of this rule in your State or within 90 days of when a storage unit is first used to store low-level mixed waste for which

you claim a conditional exemption. This requirement provides us with a record of who has made a claim for the exemption. Your notification is self-implementing. You will not receive a notice of approval from EPA or your State Agency.

(e) You must certify that facility personnel who manage stored LLMW are appropriately trained. Personnel managing the hazardous portion of the waste should be trained in identifying and providing initial response to a release of chemical constituents as well as in radioactive waste management. As part of the notification process, you must certify that personnel managing the hazardous portion of stored LLMW are appropriately trained. We are proposing that the basic personnel training requirements found at 40 CFR 265.16(a)(3) satisfy the training condition for chemical waste management.

(f) You must: inventory the LLMW at least annually; inspect the mixed waste at least quarterly for compliance with the conditions of this section; update your records of conditionally exempt LLMW at least quarterly; and keep records of the findings of these inventories and inspections. You must maintain records for three years after the waste is sent for disposal or in accordance with NRC requirements whichever is longer. An important part of assuring that you comply with the conditions proposed in today's rule is our requirement that you perform regular inspections of the facilities storing exempted waste, as well as inventory the waste to prevent loss or other mismanagement. Records of these activities must be kept long enough to assure us of consistent compliance with exemption conditions.

(g) You must maintain an accurate emergency contingency plan which you develop and provide to all local authorities who may have to respond to an emergency. Your contingency plan must describe emergency response arrangements with local authorities, describe evacuation plans, list the names, addresses and telephone numbers of all facility personnel qualified to work with local authorities as emergency coordinators, and list emergency equipment. (The majority of mixed waste generators have a plan that describes many of these emergency response arrangements, see 40 CFR part 265, subpart D.)

We propose these conditions as the minimum necessary to ensure that LLMW is properly managed, so as to avoid potential adverse impact on human health or the environment. We believe that these conditions will provide a strong incentive to properly manage the waste, and that the regulatory framework imposed by the NRC makes mismanagement of these wastes unlikely. Because of the importance of the conditions, we propose that if you (as a generator) fail to meet any one of them, then your waste will no longer be conditionally exempt and will be subject to full RCRA Subtitle C regulation.

The exemption does not replace the permitting requirements currently required for treatment, storage, and disposal facilities (TSDFs) who manage other generator's wastes and who typically manage much larger volumes of waste. By limiting the exemption to generators, we believe that the likelihood of significant human health or environmental consequences of mismanagement will be minimal due to the amount of waste generated at these sites. Nevertheless, we request comment on whether we should include in the conditional exemption for storage those mixed waste treatment facilities that manage wastes from other generators. Comments received on the ANPR generally did not agree with including such a TSDF in the entities eligible for a conditional exemption for storage of LLMW. (See docket for summary of ANPR comments.) We are interested in additional information regarding the safety of commercial TSDFs that could provide a basis for expanding the scope of the exemption to include off-site storage at commercial TSDFs.

3. Whom Should You Notify if You Want to Claim an Exemption?

To claim a conditional exemption for stored low-level mixed waste you, as the generator, must certify that the facility and waste meet all the proposed conditions in § 266.230 and must notify us (EPA or the Authorized State Agency) of each storage unit where waste will be stored for which you claim a conditional exemption. Such notification will enable us to know which wastes and which storage units are conditionally exempt. We propose that you, the owner or operator of a facility generating low-level mixed waste, notify us in writing either within 90 days of the effective date of the final rule in your State, or within 90 days of when a storage unit is first used to store LLMW for which you claim a conditional exemption. (See the list of conditions a generator must meet to qualify for a conditional exemption for stored LLMW.) This notification is self-implementing, although we may use our inspection and information collection authorities to verify whether you are meeting the conditions.

You must report in writing to us (or a RCRA Authorized State Agency), with a copy to NRC, any failure to meet a condition within 30 days of learning of the failure. If the failure to meet the conditions has the potential for endangering human health or the environment then you, the generator, must notify us orally within 24 hours and take steps outlined in your emergency contingency plan. This requirement is to ensure the timely notification and response of emergency personnel. An oral or written report regarding failure to meet the conditions does not relieve you, the generator/licensee, of NRC requirements. You must also notify the NRC if the failure triggers notification requirements under NRC regulations for the radioactive material.

4. What Records Must You Keep for the Exemption?

You must keep records of your initial notification, as well as your LLMW inventories and inspections. Records must be kept for three years after the stored waste is sent for treatment or disposal, or in accordance with NRC requirements, whichever is longer. You must update your records regularly. At a minimum, you must inventory the waste annually, inspect the waste quarterly, and update records of conditionally exempt LLMW quarterly. An important part of assuring that a generator is complying with the conditions proposed in today's rule is requiring the generator to perform regular inspections of the units storing exempted waste, as well as inventorying the waste to prevent loss or other mismanagement. Records of these activities must be kept to assure us of consistent compliance with exemption conditions.

5. How Can Your Stored Waste Lose the Exemption?

Your stored waste will lose a conditional exemption if, after claiming a conditional exemption, you subsequently fail to meet one or more of the conditions. If your stored waste no longer meets one or more of the exemption conditions, your mixed waste may be fully regulated under RCRA Subtitle C as a hazardous waste as described in § 266.235. (This consequence and its ramifications for mixed waste management are discussed under the notification, and implementation and enforcement sections of the proposed rulemaking.)

6. Can Your Exemption be Reclaimed if You Fail to Meet a Condition?

This proposed conditional exemption rulemaking envisions a self-implementing process. The exemption is lost at the time of non-compliance. EPA needs to take no action to remove the exemption. However, if your waste loses the conditional exemption, you may reclaim your exemption if you return to compliance with all conditions in § 266.230. You must send the RCRA program agency a written notice that you are reclaiming your exemption. Your notice must do the following:

- Explain the circumstances of the failure which caused your waste to lose the exemption;
- Certify that your waste is in compliance with all conditions as of the date you reclaim the exemption;
- Demonstrate that the failure is not likely to recur because of specific steps (list them) you have implemented in your LLMW-related compliance activities; and
- Include any additional information you would like us to consider regarding your reclaim notice.

If subsequently we find that a reclaimed conditional exemption is inappropriate because it is not protective of human health or the environment, then we may terminate the conditional exemption which was reclaimed.

C. How Will Implementation and Enforcement of the Conditional Exemption for Storage and Treatment of LLMW Take Place?

1. Is This a Self-Implementing Rule?

Yes, a conditional exemption is in effect as of the date of the claim, and is lost automatically when the generator fails to comply with the conditions.

2. How Will We Enforce the Proposed Storage Exemption?

We will consider non-compliant facilities to be subject to RCRA Subtitle C from the time of noncompliance. Utilities or other LLMW generators that claim the conditional exemption, but fail to store and/or treat the LLMW in compliance with the provisions of the exemption, would no longer be exempt from the applicable provisions of RCRA. Moreover, imminent and substantial endangerment provisions under § 7003 of RCRA will continue to apply to conditionally exempt mixed waste as a safeguard in the unlikely event of a release which could pose a health or environmental threat.

We are proposing the storage exemption because of the regulatory framework in place governing low-level radioactive component of LLMW. The NRC has a ''General Statement of Policy and Procedure for NRC Enforcement Actions'' (NUREG–1600) which states the NRC's policy regarding enforcement. This policy provides significant consequences for violating NRC or license requirements and takes into consideration the specific circumstances of a particular case. For example, if a nuclear power plant is found to have violated the NRC license, or tie-down conditions of the license (see definition at the beginning of this preamble), the nuclear power plant (and the responsible person) may be subject to substantial civil and criminal penalties. Based on these provisions, licensed facilities have incentives to properly manage stored waste.

D. What Background Information Did we Use for This Proposal?

To determine the protectiveness of NRC management requirements for LLMW, we researched the LLW storage provisions of NRC and material licenses, reviewed NRC compliance data on violations related to storage of LLW, and compared the regulatory framework of EPA and NRC related to waste management. Overall our comparison studies found that safeguards were in place which would ensure the protection of human health and the environment during storage of LLW and LLMW.

Review of NRC License Requirements

We researched NRC's regulatory and licensing framework under which low-level waste (LLW), and therefore LLMW, is stored by waste generators. We examined provisions concerning the on-site storage of LLW to assess whether these requirements are protective of human health and the environment with respect to potential releases of hazardous waste constituents. We found that NRC and Agreement States regulate licensees through the issuance of performance-based regulations, regulatory guides, generic communications (Generic Letters and Information Notices), and NUREGs. NRC uses these tools to guide licensees on how to meet the intent of the regulations. These documents work together to enable the NRC and Agreement States to ensure that nuclear power facilities and other licensees are operating in a safe manner. For example, on November 10, 1981 NRC issued Generic Letter 81–38, ''Storage of Low-Level Radioactive Wastes at Power Reactor Sites,'' and enclosure, ''Radiological Safety Guidance for Onsite Contingency Storage Capacity.'' In this generic letter, NRC discussed its position on proposed increases in storage capacity for low-level wastes generated by normal reactor operation and maintenance and stated that the safety of the proposed increase in capacity must be evaluated by the licensee under the provisions of 10 CFR 50.59. The NRC also attached a radiological safety guide to this letter. This guide was developed for the design and operation of interim contingency low-level waste storage facilities, and stated that necessary design features and administrative controls would be dictated by such factors as the waste form, concentrations of radioactive material in individual waste containers, a total amount of radioactivity to be stored, and retrievability of waste. NRC also noted that this guidance document should be used in the design, construction and operation of storage facilities and that the NRC would judge the adequacy of 10 CFR Part 50.59 evaluations based on compliance with the guidance. (NRC also referenced IE Circular No. 80–19, dated August 22, 1980, as providing information on preparing 50.59 evaluations for changes to radioactive waste treatment systems).

Though NRC regulations found in the Code of Federal Regulations concerning the generation, storage, and treatment of LLW are performance-based (for example, no releases/leaks), rather than prescriptive as in RCRA (where types of drums and waste management are specified to prevent leaks), the NRC-enforceable tie-down conditions found in individual licenses based on our review provide adequate protection to human health and the environment from exposure to hazardous wastes during storage as well as RCRA regulatory requirements. A compilation of the NRC documents that we reviewed can be found in the docket for today's proposal. (See Ref. 3, EPA's compliance history review.) A discussion of our evaluation of NRC's licensing framework and how it provides protection of human health and the environment when compared with the RCRA regulations is discussed in a later paragraph.

Research on Compliance Records of NRC and Agreement State Licensees

In addition to comparing NRC's and our storage requirements, we researched compliance records related to NRC radiation controls for nuclear power plants and other licensees, to determine if there were storage-related releases or mismanagement of LLW. To provide a baseline for the comparison of NRC LLW violations, we queried two of EPA's generator information management systems—the Biennial

Reporting System (BRS) and the Resource Conservation and Recovery Information System (RCRIS)—to obtain the number of RCRA violations.

Using BRS data for 1995, 18,497 facilities were identified as having generated hazardous waste (including small quantity generators). These ''records'' were merged with the information from RCRIS and then sorted by RCRIS violation area codes. The violations were sorted by group (generator, other, treatment, and transporter) and by state. Based on this process, we identified a total of 4,547 violations by a total of 1,352 facilities (or 7.3% of the 18,497 facilities). Of the 4,547 violations, 3,355 resulted from the noncompliance with the generator requirements (manifesting, record keeping, time-in-storage, reporting, etc.), and of the 3,355 generator violations, 142 involved mixed waste.

To review the NRC facility compliance records, we reviewed a number of enforcement reports for both NRC enforced and Agreement State enforced licensing programs. We did not review every licensee's record. However, enough data were reviewed to demonstrate that the number of violations reported (on a percentage basis) by NRC for both nuclear power reactors (directly licensed by NRC) and material licensees (generally licensed by Agreement States) compares favorably with the percentage of violations reported by EPA. Fines, penalties, and other consequences serve to deter violations. Based upon the compliance data, the industries' record is good and mismanagement of stored mixed waste is unlikely. We conclude that regulation under Subtitle C is unlikely to significantly improve that record.

For further information on applicable NRC regulations refer to 10 CFR part 20 subpart I. Information regarding NRC's regulations, or guidance documents may be obtained by either contacting the NRC Public Document Room, at 2120 L Street, NW, Lower Level, Washington, D.C. 20037 (202–634–3273 or 800–397–4209, Monday through Friday, 8:30 a.m. to 4:15 p.m.) or by visiting NRC's Internet web page at *http://www.nrc.gov*.

Comparison of Regulatory and Management Requirements of EPA & NRC

We compared NRC documents used in license preparation with the permitting framework established under RCRA. The technical design and operating standards of the NRC licensing program meet or exceed RCRA standards in virtually all respects, though there were differences in certain procedural requirements and in areas unrelated to actual discharge of hazardous waste from storage (e.g., unit closure requirements). Based on our review, we do not believe these differences undermine protection of human health and the environment, or that the superimposition of RCRA specific standards significantly increases protection. (See Ref. 4, EPA's comparison of EPA and NRC storage requirements). Relevant NRC licensing criteria are in the docket for today's rulemaking, and may also be obtained by contacting the NRC public document room at 202–634–3273 or accessing the NRC web site (http://www.nrc.gov). These criteria, while designed primarily to minimize radiation risk, also address risk posed by byproduct material in general, including hazardous constituents. Because of the unique nature of mixed wastes, migration of hazardous constituents does not occur except in the presence of radionuclides. Therefore, activities performed by a licensee to safely store or address the release of the radioactive portion of the mixed waste will also result in the safe storage of the chemical components of the LLMW matrix.

The applicability of NRC licensing standards to mixed waste in storage is the major reason for our belief that—in specified circumstances—it is not necessary to also subject these wastes to RCRA storage regulation.

Conclusions

These studies demonstrate that the NRC regulatory and licensing program will adequately control risks from hazardous constituents as well as radioactive material. There are safeguards in place based upon the NRC regulatory framework during the conditionally-exempt storage of LLMW. As stated by the court in the MMR ''where a waste might pose a hazard only under limited management scenarios, and other regulatory programs [the NRC] already address such scenarios, EPA is not required to classify a waste as hazardous waste subject to regulation under Subtitle C.''

E. What Was the Response of Commenters to the ANPR?

On March 1, 1999, we published and advance notice of proposed rulemaking (64 FR 10063) for three reasons. First, we wanted to introduce potential strategies for making our regulations more flexible for generators that treat and/or store LLMW on site. Second, we asked members of the regulated community and general public for feedback on our strategies and whether we should consider other approaches for providing relief from the dual, EPA and NRC, regulation of mixed waste. Lastly, we asked LLMW generators to provide us with additional information on the volumes, composition, and management practices (including procedures and associated costs of treatment and storage) of their mixed waste.

We received comments from 69 commenters who represented academia, TSDFs, contractors, federal agencies, medical institutions, industrial users, the nuclear power industry, the public, state governments, and trade groups/law firms.

Availability of Comment Summary

Copies of all the public comments received by EPA, along with our comment summary document are available for viewing in either hard copy or electronic format by following the instructions presented in the beginning of this document. (See Ref. 5, a summary of comments received on the ANPR.) A detailed response to significant comments received on the ANPR and the proposal will be available in the docket for the final rulemaking.

1. What Comments Did We Receive Concerning a Conditional Exemption for Storage?

We received a favorable response from most commenters concerning a conditional exemption for storage. The vast majority (87%) of the commenters supported the concept of providing regulatory flexibility to generators of LLMW. Many of these commenters made suggestions for either increasing or decreasing the level of flexibility and the degree to which EPA should remain involved in the implementation and enforcement of any conditional exemption. Other commenters (6%) provided suggestions for improving the effectiveness of the proposed approaches, but remained silent as to whether they supported the overall concept. The remaining commenters (7%) opposed EPA's concept for various reasons.

We received 47 comments supporting the concept of a conditional exemption for on-site storage of LLMW at nuclear power plants. Several commenters, primarily universities, suggested the conditional exemption should be extended to wastes stored ''off-site.'' Thirty-four (72% of the supportive commenters) commenters believed that the scope of the conditional storage exemption should include all material licensees that have either a NRC or Agreement State license for LLMW. Several commenters noted that non-reactor facilities generate most of the mixed waste in the United States and

are faced with the same compliance and management issues as reactor facilities.

We also received comments from six commenters that the conditional exemption for storage should not be extended to commercial TSDFs because these facilities provide such services and have RCRA Subtitle C permits to do so. As such, they require no relief. Commenters stated that: such facilities are in the business of managing LLMW for compensation and should be regulated accordingly; and the duration of storage at such facilities may be driven by the time requirements under the facility's RCRA permit and an exemption that would void those time frames could potentially affect the facility's ability to control waste inventory.

2. What Were the Comments on Decay-In-Storage?

We received 32 comments on the proposed conditional exemption for Decay-in-Storage (DIS). All commenters supported relief in this area. Two commenters opposed the DIS proposal laid out in the ANPR. Both of these commenters, stated that they preferred a strategy with more flexibility to manage wastes that (1) have longer half-lives than those prescribed by the NRC, (2) are difficult to dispose of, (3) do not yet meet NRC's criteria of ''cannot be distinguished from background'' after 10 half lives, and (4) begin decay at different times.

We received 23 comments on when LLMW would reenter the RCRA system. Seventeen commenters supported the strategy to bring waste back into the RCRA system once the LLMW had either ''decayed'', ''decayed to background levels'', or ''decayed to insignificant levels.'' One commenter noted that often non-detectable background levels are not specifically established by the NRC and vary from state to state, so background levels at one facility may be different than background levels at another facility. This commenter also stated that since AEA low-level waste requirements protect the waste after it decays, as well during the decay process, there should be no urgency to revert back to RCRA management. A different commenter echoed the same concern that often ''indistinguishable from background'' is not the same as ''no radioactive material in waste'' which is a requirement prior to acceptance at many commercial waste treatment facilities. This commenter added that EPA should make sure that once the waste decays to NRC license levels (indistinguishable from background) it must be accepted by commercial treatment facilities, even if the radiation survey finds extremely small concentrations of radioactive material in the waste.

3. What Comments Did We Receive Concerning Treatment of Waste in Storage?

We received 36 comments regarding the scope of the exemption. Of these comments, 11 commenters supported the conditional exemption, 23 supported the conditional exemption with recommendations to expand the exemption, and two specifically opposed the conditional exemption. One commenter believed that the treatment of mixed waste should be performed on-site in a tank, container, or containment building in accordance with the generator's NRC license requirements. Other commenters believed that EPA should not limit the exemption to treatment in containers, tanks, or containment buildings. One such commenter supported a treatment exemption for treatment in enclosed units with filtered exhaust systems. Other commenters noted that simple treatments, such as neutralization of acids and bases, ion exchange, small scale distillation, and similar measures performed by qualified and authorized personnel should be included without restriction. Another commenter noted that the definition of ''tank or container'' should include, but not be limited to, small-volume containers such as carboys, liquid scintillation vials, and other commonly-used containers.

4. What Comments Did We Receive Concerning Possible Conditions for a Storage Exemption?

We received numerous comments regarding the possible conditions that must be met to qualify for an exemption. The most significant conditions discussed by the commenters involved the notification and identification of units, and noncompliance. We discuss these categories of comments below.

a. What did commenters say concerning notification and identification of units?

We received comments from 22 commenters regarding the proposal to establish notification requirements for LLMW facilities applying for conditional exemption from RCRA hazardous waste regulations. Eleven commenters endorsed the proposal. Another seven commenters recommended modifications to the proposal. Four commenters opposed the proposal, maintaining that the Agency identification number in RCRA or facility designation in existing NRC licensing requirements served this purpose. (See ''Summary of Comments from March 1, 1999 ANPR'' in docket.)

Of the 11 commenters who endorsed the proposal, two commenters agreed that requiring the owner/operator to notify EPA within 90 days is a reasonable requirement. Another commenter pointed out that notification was essential to help prevent confusion regarding the regulatory status of a particular unit, particularly during an EPA inspection. The other nine commenters contended that the proposal establishing the notification requirement and the proposal requiring the owner/operator to possess a valid NRC and Agreement State license are the only two conditions that are necessary to exempt facilities from RCRA regulations. Of the seven commenters who suggested modifications to the proposal, four believed that the notification requirements should be kept as simple as possible.

b. What were commenters views concerning non-compliance and RCRA enforcement?

Sixteen commenters addressed the proposal dealing with violations and the related proposal to include a reporting requirement as a condition of the exemption. One commenter endorsed the overall proposal, while seven commenters either sought clarifications about the proposal or suggested modifications to it. Eight commenters opposed the proposal.

Of the seven commenters who sought clarifications about the proposal, four commenters said we should consider revocation of the conditional exemption only for serious or repeat violations, and especially in instances where environmental and health and safety issues were involved. Of the eight commenters who opposed the proposal, six believed that notifications should be limited to events that are reportable under the conditions of the applicable NRC license.

c. What did commenters say about notification of violations & reporting requirements?

Two commenters supported reporting of noncompliance with the conditions of the exemption. One commenter agreed that any releases with potential for significant environmental impact should be reported to EPA as is currently required for radionuclides and other hazardous materials. One commenter agreed with the proposed requirement for oral reporting within 24 hours for violations of the NRC license that results in endangerment to human health and the environment, noting that

this provision is consistent with existing NRC requirements. However, this commenter did not agree with the requirement for a written report within 5 days, noting that the standard NRC requirement for submitting a written report to NRC is 30 days. The commenter recommends that the reporting requirements should not be more stringent than NRC requirements.

VI. Transportation and Disposal Conditional Exemption For Mixed Waste and Eligible NARM

Regarding transportation and disposal, we are proposing regulatory flexibility related to the manifest, transportation, and disposal of treated LLMW or eligible NARM. In the sections below, we will discuss the following topics: the regulatory relief we are proposing; the applicability of the proposal; the point at which the exemption would apply; implementation and enforcement aspects of the proposal; the rationale behind the requirements that we are proposing; the technical analysis we have conducted on the proposed option; and stakeholder issues.

A. What Regulatory Relief are we Providing for Transportation and Disposal?

We are proposing to conditionally exempt LLMW or eligible NARM from RCRA Subtitle C hazardous waste manifest, transportation, and disposal requirements if all of the proposed conditions are met. To be eligible for the exemption, the RCRA Subtitle C exempted waste must be managed as a low level radioactive waste (LLW) or NARM waste in accordance with NRC, or Agreement State regulations. This proposal is based on our determination that LLMW or eligible NARM mixed waste, if managed pursuant to the NRC or Agreement State regulations for manifest, transportation and disposal of LLW, would provide sufficient protection of human health and the environment during the manifest, transportation and disposal of a treated RCRA hazardous waste (See section VI. G. for details).

With today's action, we anticipate that MW generators and treaters would have considerably more disposal capacity available to them. Currently, there is only one commercial mixed waste disposal facility while there are three LLRWDFs licensed by the Agreement States. Consequently, commercial MW generators, with an estimated annual waste generation rate of approximately 140,000 cubic feet of LLMW, would be able to move those wastes that can be treated to meet LDR standards to disposal.

The conditions for the transportation and disposal exemption are listed in § 266.315 which includes the following:

- Meet LDR treatment standards in accordance with one of the following:
- Treatment at a RCRA-permitted mixed waste treatment facility;
- Treatment on site under the provisions of the conditional exemption from the RCRA storage and treatment requirements proposed today for NRC or Agreement State licensees; or
- Without treatment, if the ''as generated'' hazardous waste mixed with LLW or eligible NARM meets the LDR treatment requirements.
- Send a notification package to the following agencies and receive written confirmation that they have received the package:

—The RCRA program agency with jurisdiction over your MW;
—The RCRA program agency in the State where the NRC or Agreement State-licensed low level radioactive waste disposal facility (LLRWDF) receiving your waste is located; and
—NRC or Agreement State Agency regulating/licensing the LLRWDF receiving your waste for disposal.

- Meet NRC 10 CFR 71.5 or Agreement State transportation requirements, and NRC 10 CFR 20.2006 or Agreement State manifest requirements even if you self-regulate under the authority of Atomic Energy Act.
- Ensure that the exempted waste (meeting LDR treatment standards) is disposed at a LLRWDF pursuant to NRC or Agreement State regulations in accordance to 10 CFR 61. (We are requiring that the RCRA-exempt LLMW, or eligible NARM, be disposed in containers that meet the waste packaging, waste form and waste integrity requirements of NRC.)
- Retain all records related to the conditional exemption (including the necessary LDR records) as specified in § 266.365.

Exempted waste would continue to be regulated by NRC or Agreement State during subsequent transportation and disposal. We believe NRC or Agreement State regulations for the manifest, transportation, and disposal provide adequate protection for human health and the environment from the risks posed by LLMW treated to LDR treatment standards. For transportation, as discussed in VI.E.3., treating waste to LDR treatment standard levels reduces toxicity and mobility of hazardous constituents remaining in the waste. Thus, transportation of the treated waste according to the requirements for low level radioactive waste would be adequate. In addition, the exempted waste must not be in a liquid form, as specified by NRC or Agreement State regulations for the disposal of LLW. Therefore, if spilled during transportation, the exempted waste could be contained relatively easily. As a result, the likelihood of exempted waste contaminating the environment and endangering human health during transportation would be low.

We also believe that LLMW, or eligible NARM, meeting LDR treatment standards poses insignificant risks when disposed of in LLRWDFs according to the requirements set by NRC or Agreement State according to 10 CFR 61. Our technical analysis showed that NRC or Agreement State requires adequate controls to protect against radiation hazards at LLRWDFs. We believe that these landfills would also protect against the chemical hazards of LLMW in the absence of RCRA disposal requirements, so long as the LLMW, or eligible NARM, meets the LDR treatment standards and is disposed at a LLRWDFs licensed by NRC or an Agreement State. (See discussion in VI. G.).

B. Applicability of the Proposal

1. To What Types of Waste Does This Rule Apply?

The conditional exemption for disposal applies only to LLMW (a RCRA hazardous waste as defined in 40 CFR part 261 mixed with a low level radioactive waste as defined in 10 CFR 61.2) or eligible NARM (as defined in this proposal—a RCRA hazardous waste mixed with a NARM waste which meets the acceptance criteria of a LLRWDF licensed by NRC or an Agreement State). The exemption does not apply to a RCRA hazardous waste mixed with high level radioactive waste, or transuranic waste.

We are proposing to include eligible NARM waste in the conditional exemption at the request of a state agency regulating the radioactive material. (See Ref.11.) NARM waste is not regulated by NRC. Neither is NARM currently regulated under RCRA Subtitle C authority. In practice, NARM waste has been regulated by the States under State law, or by DOE under DOE Orders. Most of the states are currently regulating NARM waste under their radiation control program. NARM waste mixed with a RCRA hazardous waste is managed under both RCRA and state radiation control programs in most states. Because of this dual regulation, we are proposing that the exemption

also apply to eligible NARM waste. However, we are requiring that the NARM waste meet the acceptance criteria of a LLRWDF licensed by NRC or an Agreement State in accordance with 10 CFR 61. This restriction is necessary because our technical analysis is based in part on licensing requirements under 10 CFR 61. We are seeking comments and supporting information concerning the applicability of this transportation and disposal proposal to eligible NARM waste.

2. Who Could Benefit From this Proposal, and What is the Profile of Their Waste?

All generators of LLMW or NARM waste can potentially benefit from this proposal, if their MW meets all the specified conditions. Some examples of these generators are listed at the beginning of the preamble in Table 1 under ''Who is Eligible for This Rule''. We estimate that this rulemaking could apply to the LLMW generated and stored by over 1,000 industrial facilities and laboratories in the U.S. Approximately 108,000 cubic feet of LLMW is generated annually by these facilities, and an additional 4,000 cubic feet of legacy waste is currently in long-term storage without options for treatment and/or disposal. In addition, DOE generates approximately 400,000 cubic feet annually, with 4.4 million cubic feet of legacy waste in storage. (See Ref.14 and 17 for details on waste volumes and cost-benefit analysis.)

According to the available information, DOE operations currently face mixed waste disposal capacity issues similar to those experienced by the commercial sector. This proposal would only provide partial relief for DOE due to concerns expressed by the States regarding disposal of the RCRA-exempted LLMW at DOE's LLRWDFs (see VI. H). However, DOE has been working with the States to establish additional disposal capacity for its LLMW.

3. What Other Regulatory Relief Provisions May Apply?

Generators of LLMW or NARM that is not eligible for the proposed conditional exemption for transportation and disposal may petition EPA to get their specific waste stream delisted from RCRA Subtitle C under the RCRA Delisting Program (Contact the EPA Regional delisting coordinator for details.)

C. What is the Point of Exemption?

We are proposing that LLMW or eligible NARM be exempted from RCRA Subtitle C requirements once the generator has met all pre-transport requirements under § 266.315. Specifically, the point of exemption occurs when the waste is placed on the transportation vehicle bound for disposal at an NRC or Agreement State-licensed LLRWDF. A shipment ''bound for disposal'' includes any shipment originating from the generator that is transported by one or more transporters. However, the shipment must not go to any other facility en route to the designated LLRWDF, other than to a transfer facility meeting the requirements of 40 CFR 263.12. The exempted waste would not have to be managed according to RCRA Subtitle C requirements during transportation and final disposal at the LLRWDF. We are proposing the point of exemption as described above for the following reasons:

- The exempted waste will continue to be managed in accordance to the AEA because of the radioactive component of the waste.
- The risks posed by exempted waste when transported and manifested are adequately addressed by the NRC transportation and manifest requirements.
- The risks posed by the exempted waste when disposed of in a LLRWDF are adequately addressed by the requirements set by NRC or an Agreement State in accordance with 10 CFR 61.
- The exemption would reduce the generator's requirements to comply with duplicative regulations during transportation and disposal, in that NRC regulations have been shown to be as protective as RCRA regulations.

In conclusion, we set the point of exemption as proposed primarily because we believe that transportation, tracking, and disposal of waste meeting the LDR treatment standards can be safely managed according to similar regulations of NRC. The end result is that regulatory burden can be reduced because NRC regulations provide comparable protection.

D. Implementation and Enforcement

1. How Will the Transportation and Disposal Conditional Exemption Be Implemented?

We are proposing that the transportation and disposal conditional exemption be self-implementing. No prior governmental approval or review of documentation is required before a generator's qualified waste exits RCRA Subtitle C manifest, transportation, and disposal requirements. This basic framework is consistent with most other hazardous waste exemptions and exclusions, such as the LDR program, where generators and treaters can certify that their hazardous waste meets LDR treatment standards and qualifies for land disposal, without prior governmental approval. Furthermore, it is also consistent with provisions discussed in the HWIR99 notice related to the concentration based exemption and exclusions from the definition of solid waste found in 40 CFR 261.4(b).

We are proposing self-implementation for the transportation and disposal conditional exemption because we believe that there is no substantial advantage to be gained from requiring approval for an exemption. Furthermore, the waste exiting RCRA requirements would continue to be managed under an alternate regulatory program (NRC or Agreement State regulations) that would provide comparable protection for human health and the environment. This would also be true for generators like DOE who self-regulate under the AEA, because their waste would also be disposed at a LLRWDF regulated by NRC or Agreement State. Therefore, we believe that under the proposed self-implementing method, the waste will continue to be properly managed while the regulatory burden is reduced. In addition, self-implementation has the following advantages:

- The exemption can take effect more quickly since approval from the RCRA program agency is not necessary;
- It reduces the generator's burden in claiming the exemption;
- It does not impose burden, or time restrictions on the RCRA program agency to review the notification package while maintaining jurisdiction; and

However, self-implementation does not mean that the RCRA program agency does not have a role in overseeing the conditional exemption. The RCRA program agency will be notified of the exemption, and will have access to all documentation related to a claim (See VI.E.2 of this preamble).

While the RCRA regulatory agencies may review a generator's exemption claim, the lack of such a review would not be an indication of their approval of the exemption claim. That is, the confirmation that the RCRA program agency has received the exemption notification package would not imply that they have reviewed or approved it. Therefore, the exempted waste will still lose its exemption whenever it is discovered that any of the required conditions is not met.

The RCRA program agency may conduct inspections and review the records to determine whether the

generator is in compliance with the conditions of this exemption. The RCRA program agency can use this information to support enforcement action. Concerned citizens can bring to the regulator's attention any circumstance that might aid authorities in monitoring and enforcement efforts, or file a citizen suit under RCRA section 7002 against a generator for failure to comply with the conditions for exemption.

2. What Happens if Your Waste No Longer Meets the Conditions of the Transportation and Disposal Conditional Exemption?

When any exemption condition is not met, your waste loses its exemption status and may be fully regulated under RCRA subtitle C as a hazardous waste. You could also be subject to enforcement actions which could result in fines and penalties. RCRA subtitle C sections 3008 gives us the authority to commence enforcement actions and assess fines and penalties. Examples of activities that could lead to an enforcement action against you include misclaiming of a conditional exemption, failure to meet the conditions of the exemption, or providing erroneous information to the disposal facility.

3. Are There any Additional Requirements You Must Meet?

Yes, the additional requirements of the transportation and disposal conditional exemption are listed under the proposed sections § 266.325(b) and § 266.330(b). Under these sections, you are required to notify the LLRWDF of the exempt status of your waste before you ship it to the facility for disposal (see VI.E.2.d). These requirements are obligations that you are required to meet at all times. While your exemption status would not change if a requirement was violated, you could be subject to RCRA enforcement actions which could result in fines and penalties.

4. Can Your Exemption be Reclaimed if You Fail to Meet a Condition?

This proposed conditional exemption rulemaking envisions a self-implementing process. The exemption is lost at the time of non-compliance. EPA needs to take no action to remove the exemption. However, if your waste loses the conditional exemption, you may reclaim your exemption if you return to compliance with all conditions in § 266.315. You must send the RCRA program agency a written notice that you are reclaiming your exemption. Your notice must do the following:

- Explain the circumstances of the failure which caused your waste to lose the exemption;
- Certify that your waste is in compliance with all conditions as of the date you reclaim the exemption;
- Demonstrate that the failure is not likely to recur because of specific steps (list them) you have implemented in your LLMW-related compliance activities; and
- Include any additional information you would like us to consider regarding your reclaim notice.

If subsequently we find that a reclaimed conditional exemption is inappropriate because it is not protective of human health or the environment, then we may terminate the conditional exemption which was reclaimed.

Alternatively, we could specify a waiting period for reclaiming a disposal exemption. The waiting period would allow the regulatory agency time to confirm that the violation has been corrected, and is not likely to recur. This may be prudent when a conditional exemption has been lost. Generally, it takes time to schedule and conduct confirmation inspections. Self-implementation of your reclaimed exemption may not allow the RCRA program agency time to confirm that an infraction has been corrected. As a result, waste could be inappropriately shipped off-site for disposal. Therefore, we are seeking comment on whether to provide for a 90-day waiting period before your reclaimed exemption for disposal is final.

5. What Can a LLRWDF do to Reduce the Potential Applicability of RCRA Authorities?

As discussed in VI.G. we believe that disposal of LLMW, treated to LDR standards, in a designated LLRWDF is protective of human health and the environment, and we do not expect the exempted waste to pose a risk once properly disposed. We believe a LLRWDF can greatly reduce the potential applicability of RCRA authorities by taking steps to ensure that the exempted waste has achieved the required LDR treatment standards. During our discussion with the LLRWDFs (Ref.9), they indicated that they would consider conducting independent waste analysis to ensure that the waste accepted do meet the LDR treatment standards. Additionally, we would encourage open communication between the waste generators and the LLRWDFs regarding waste information.

E. What Conditions Must You Meet Prior to Claiming the Transportation and Disposal Exemption?

This section discusses the rationale behind the conditions of the exemption.

1. Why Are we Requiring LDR Treatment?

The hazardous constituents in waste eligible for the exemption must first be treated to meet the RCRA LDR treatment standards specified in 40 CFR 268.40—268.48. The treated waste also must meet the definition of non-wastewater as defined in 40 CFR 268.2(d). We believe that LLMW or eligible NARM waste should meet LDR treatment standards, and be managed in accordance with NRC or Agreement State requirements for LLW to ensure protection of human health and the environment.

Like any hazardous waste destined for land disposal, LLMW must meet LDR treatment standards prior to its disposal at a mixed waste disposal facility (with a RCRA hazardous waste disposal permit and an NRC or Agreement State license for radioactive waste disposal). Compliance with the LDR treatment standards ensures that the toxicity and mobility of the hazardous waste constituents is reduced. Our LLMW transportation and disposal conditional exemption is based upon our determination that the LLMW, or eligible NARM waste, which meets the LDR treatment standards (thereby substantially reducing the toxicity and mobility of the hazardous constituents in the waste) is rendered ''nonhazardous'' when disposed in accordance with NRC or Agreement State regulations.

In the Hazardous and Solid Waste Amendments (HSWA) of 1984, Congress prohibited land disposal of hazardous waste unless the waste undergoes treatment to minimize threats to human health and the environment. The statute requires that treatment standards established by EPA will substantially diminish the toxicity or mobility of hazardous waste such that short-and long-term threats to human health and the environment are minimized. See RCRA section 3004(m) 42 U.S.C. 6912(a), 6921, and 6924. Over the last 15 years, EPA has responded to the statutory mandate by developing through a series of rulemakings treatment standards for hazardous waste based on the best demonstrated available technology (BDAT) for treating the waste. With the promulgation of the most recent ''Phase IV'' Rule (63 FR 28556, May 19, 1998), EPA has promulgated treatment standards for

most hazardous wastes. This effort will continue as we promulgate new hazardous waste listings or otherwise identify new hazardous wastes.

Furthermore, hazardous wastes (other than wastewaters) meeting the LDR treatment standards, with a few exceptions, must be disposed of at a RCRA Subtitle C hazardous waste disposal facility. However, characteristic wastes that are rendered non-characteristic may be disposed of as non-hazardous solid waste provided that they meet LDR treatment standards, including standards for underlying hazardous constituents (§ 268.2(i)). Wastes that have been delisted (§ 260.22) may also be disposed of as solid waste.

Please note: In the following sections the discussion on existing LDR treatment requirements are meant to provide reference information for the reader. We are not taking comment on any existing LDR requirements.

In the following sections of VI.E.1.a, we discuss different types of RCRA hazardous wastes and summarize the existing applicable RCRA LDR treatment standards for them.

a. *What are the existing RCRA LDR treatment requirements for various types of LLMW?*

In the following discussion, we provide information regarding existing RCRA LDR treatment requirements for various types of waste. A table identifying the types of RCRA hazardous waste commonly found in LLMW is provided as background material in the RCRA Docket (Ref. 10)

i. LLMW that is a listed hazardous waste (F, K, P, and U waste)

LLMW that contains, or is mixed with or derived from, a hazardous waste listed in 40 CFR Part 261, subpart D has to be treated to meet the LDR treatment standards specified for these waste streams in 40 CFR 268.40 before it is eligible for the transportation and disposal exemption. Based on the available data, the listed hazardous waste codes most commonly associated with LLMW are F001—F005, the codes for spent solvent wastes.

ii. LLMW exhibiting hazardous characteristics (D001–D043)

Currently, a characteristic LLMW becomes a low-level radioactive waste and is managed as such once it has been decharacterized. Under this situation, a generator would not need to claim the transportation and disposal exemption, nor meet the associated conditions in order to dispose the resulting non-RCRA hazardous, low level radioactive waste in a low level radioactive waste disposal facility. However, if a characteristic MW was treated but not decharacterized, then it continues to be a MW. You would then need to claim the MW transportation and disposal exemption and meet the associated conditions for this resulting MW in order to dispose of it in a LLRWDF. In addition, the underlying hazardous constituents (UHCs) must always be identified and treated to meet the Universal Treatment Standards (UTS) levels specified in 40 CFR 268.48.

Under current regulations, a waste exhibiting the characteristics of ignitability (D001), corrosivity (D002), reactivity (D003), or toxicity (D004–D043) must be treated to the applicable LDR treatment standards specified for those waste codes in 40 CFR 268.40 before it can be disposed on land. If meeting the LDR treatment standards also enabled the treated waste to become decharacterized, then the resulting waste can be disposed as non-hazardous waste. However, if meeting the LDR treatment standards does not enable the treated waste to become decharacterized, then the resulting waste must be disposed of as hazardous waste. (This is the case for some characteristic wastes exhibiting the characteristic of toxicity, such as Selenium.) In order for a characteristic waste exhibiting toxicity to be decharacterized, the toxic constituent must be treated to below the ''Maximum Concentration of Contaminants For The Toxicity Characteristic'' listed under § 261.24. On the other hand, the LDR treatment standards are technology based and therefore do not always achieve the levels listed in § 261.24. Therefore, a decharacterized LLMW becomes a LLW and does not need to claim the MW transportation and disposal exemption. On the other hand, a treated but not decharacterized LLMW continues to be a LLMW and would have to claim the exemption in order for it to be disposed in LLRWDF.

In addition, the UHCs must also be identified and treated to meet the UTS levels specified in 40 CFR 268.48. In 1998, EPA promulgated the LDR Phase IV Rule, revising UTS for nonwastewater forms of 12 metals (63 FR 28559–28572). The rule also required treatment of UHCs reasonably expected to be present in the toxicity characteristic (TC) waste to UTS levels.

iii. Mixed waste debris

Debris, as defined in 40 CFR 268.2(g), contaminated with RCRA hazardous waste and radioactive debris can be treated according to an alternative LDR treatment standards under § 268.45 (57 FR 37221, Aug. 8, 1992). The treated debris can then be disposed on land. The three major types of treatment methods under the LDR alternative treatment standards for debris consist of destruction, extraction, and immobilization. Under LDR regulation, any hazardous debris treated by the destruction and extraction methods are considered non-hazardous waste. As such, a MW debris meeting the requirements for extraction and destruction treatment methods can be managed as radioactive waste alone. Therefore, you would not need to claim the transportation and disposal exemption, nor meet the associated conditions in order to dispose this resulting non-RCRA hazardous, radioactive waste debris in a LLRWDF. However, for a MW debris treated via the immobilization treatment methods, the resulting waste remains a RCRA hazardous waste. Therefore, you would need to claim the exemption and meet the associated conditions in order for you to dispose the immobilized MW debris in a LLRWDF. Alternatively, a listed hazardous debris treated through the immobilization technology becomes a non-hazardous waste under § 261.3(f)(2) if the Regional Administrator determines that it is no longer hazardous, after a ''contained-in'' determination is made. Characteristic debris treated by immobilization technology can also become a non-hazardous waste if you, the generator, can demonstrate that the immobilized debris is no longer hazardous. If your treated debris is no longer hazardous, then you would not need to claim a conditional exemption in order to dispose the waste at a LLRWDF. Also, mixed waste debris treated to meet the treatment standards found in § 268.40 can be disposed of at LLRWDFs if the proposed conditions were met.

iv. Hazardous soil contaminated with radioactivity

Under current LDR treatment requirements, soils contaminated with RCRA hazardous waste must be treated to meet the universal treatment standards at § 268.48 before disposal in a RCRA hazardous waste landfill. In addition, we also promulgated alternative treatment standards for soils under the LDR Phase IV Rule (63 FR 28602–28622, May 26, 1998) to provide flexibility for remediation activities. The alternative treatment standards for soils can be found in § 268.49.

Contaminated soils treated to meet the RCRA LDR treatment standards must be disposed in a RCRA hazardous waste disposal facility, unless they are found to no longer be a hazardous waste. When the treated waste continues to be

a hazardous waste, you would need to claim the exemption proposed today in order to dispose the treated soils at a LLRWDF. However, under current LDR regulations, the treated soils can be disposed in a RCRA non-hazardous waste disposal facility if it is determined that the treated soils are no longer a RCRA hazardous waste. Under this situation, the resulting soils become a radioactive waste, and you do not need to claim the exemption proposed here today in order to dispose it in a LLRWDF.

The alternative treatment standards allow contaminated soil to be treated to remove 90% of the hazardous constituent concentrations, but not below 10 times the UTS level for those constituents. In the LDR Phase IV Rule, we determined that the technology-based ''90 percent reduction capped by 10 x UTS'' treatment standard for contaminated soil is sufficiently stringent to satisfy the core requirement of RCRA Section 3004 (m) that short and long-term threats to human health and the environment are reduced, taking into account the need to encourage remediation of contaminated soil which involves excavation and treatment of the soil. In the case of this exemption, soils placed in a NRC-regulated LLRWDF must be containerized in addition to complying with the applicable LDR treatment standards. We request comment on whether, for any reason, this conditional exemption should apply only to hazardous soils contaminated with radioactive waste and treated to LDR standards derived from the original waste codes, rather than to soils treated to alternative soil treatment standards.

v. *Hazardous and radioactive waste managed in lab packs*

As an alternative to the otherwise applicable LDR treatment standards, lab packs containing hazardous and radioactive wastes are eligible for the exemption provided the following requirements are met:

- The lab packs comply with the applicable provisions of 40 CFR 264.316 and 40 CFR 265.316;
- The lab pack does not contain any of the wastes listed in Appendix IV to part 268;
- The lab packs are incinerated in accordance with the requirements of 40 CFR part 264, subpart O or 40 CFR part 265, subpart O; and
- Any incinerator residues from lab packs containing D004, D005, D006, D007, D008, D010, and D011 are treated in compliance with the applicable LDR treatment standards specified for such wastes.

vi. *LDR variance from a treatment standard*

Today's proposal does not change the provisions for a variance from a treatment standard at § 268.44. You may continue to petition for a variance from the LDR treatment standards as discussed under § 268.44 if the established LDR treatment standards is not appropriate for your specific waste.

b. *How do you determine whether your hazardous and radioactive waste meets the LDR treatment levels?*

You must comply with the same requirements as those required under the current LDR program to determine whether your waste meets the LDR treatment standards prior to disposal. (See the LDR waste determination and testing requirements at sections 268.7(a) and 268.7(b) for hazardous waste generators and treatment facilities, respectively.

c. *What can you do to reduce radiation hazards when testing your hazardous and radioactive waste to show compliance with LDR treatment levels?*

Recognizing the public's concern over potential radiation exposure from mixed waste testing (for example, as noted in public comments on the HWIR95 proposal), we developed, in close coordination with NRC, a mixed waste testing guidance titled ''Joint NRC/EPA Guidance on Testing Requirements for Mixed Radioactive and Hazardous Waste'' to address this concern. [Interested readers can get a copy of the guidance by accessing EPA's mixed waste web site (www.epa.gov/radiation/mixed-waste/).] The primary purpose of this guidance document is to help NRC or Agreement State licensees and others in characterizing their mixed waste in accordance with RCRA regulations while keeping radiation exposure as low as reasonably achievable (ALARA). The guidance emphasizes flexibility in the RCRA testing requirements so that the ALARA concept can be incorporated.

2. Why is Notification a Condition for the Exemption?

a. *Why must you notify the appropriate RCRA program agency of your claim of the exemption?*

The notification package, referred to in § 266.325-§ 266.330 of this proposed rule, lets your RCRA program agency know about your exemption claim. The notification is especially important because as proposed, the regulation would be self-implementing. The information contained in the notification package would provide your RCRA program agency a general understanding of the nature and volume of your waste. The certification that your waste meets the LDR treatment standard provides your RCRA program agency the assurance that one of the critical conditions of the exemption has been met. Information regarding the disposal facility allows your RCRA program agency to confirm such disposal. This information would allow the agency to document, verify, and track your exemption compliance status. They can plan inspections and review exemption-related records to ensure that you are following all the conditions of the transportation and disposal exemption. They can also consider the need for possible enforcement actions if an exemption is improperly claimed. However, your RCRA program agency would be under no obligation to review the notification notice or approve the exemption claim.

b. *Why must you also notify both the RCRA program agency and NRC or Agreement State in the State where your waste will be disposed?*

We require you to notify the RCRA program agency and NRC or Agreement State at the state where the NRC or Agreement State-licensed LLRWDF is located so that they are properly informed and can take prompt and informed action, when necessary. Further, we believe that knowledge of the exemption claims should enable the regulatory agencies, in the state where the LLRWDF resides, to take a more proactive role in protecting their interests. The state regulators expressed concerns that disposal facilities might receive shipments that do not meet the transportation and disposal exemption conditions (Ref. 11).

In the event that they need to investigate any problem at the disposal facility in their State, knowledge of the exemption would allow them to communicate with the appropriate regulatory agencies and obtain additional information necessary for their investigation. Knowledge of the exemption would also facilitate and expedite communication among regulatory agencies in different states and under different regulatory authorities. LLRWDFs are licensed and regulated by NRC or Agreement State, which in some instances can be a separate regulatory agency from the RCRA agency within a state. Therefore, we are proposing that notification packages be sent to NRC or Agreement State and the RCRA program agency in the state where the RCRA-exempted waste is to be disposed. We believe this condition will not create much additional burden for you because you

already have to prepare the same notification package for their RCRA program agency. This additional notification would only require you to make and send copies of the same paper work that has already been created. Therefore, we believe this notification condition can be accomplished with minimum cost and burden while providing substantial benefit.

c. *Are you required to include the LDR test results and other related material in your notification package?*

No, we believe it is not necessary to submit detailed LDR compliance data, such as the waste analysis plan and testing data, in your notification package. The purpose of the notice is simply to inform the regulatory agencies of the exemption claim and provide a general description of the claim (for example, your identity, description and volume of the waste, and disposal location). In addition, because this rule is self-implementing, we do not see the advantage of including detailed information such as the waste analysis plan and laboratory testing results in the notification package. This is because the implementing authority is not required to make a formal decision regarding the exemption under the self-implementing scheme. The inclusion of detailed LDR compliance data would unnecessarily create additional burden and increase the cost of the regulation.

This aspect of the proposal is consistent with the existing RCRA program. The LDR program does not require generators to submit detailed waste testing information to the States. Rather, these types of information must be kept at the generator's site for at least three years. Under the transportation and disposal conditional exemption, the LDR compliance testing data would also be kept on site for three years from the time the exemption is claimed. Therefore, the RCRA program agency would always have access to the detailed information regarding LDR compliance.

d. *Why do you have to notify the LLRWDF receiving your exempted waste of the exempted status of your waste?*

We are requiring you to notify the LLRWDF for two reasons. The first reason is to let the LLRWDF know that the shipment contains the exempted waste so that they can take actions that they deemed necessary to protect their facilities. The second reason is to allow future identification of a shipment that had contained an RCRA-exempted waste.

Clearly, a LLRWDF's willingness to receive the exempted waste is essential in achieving regulatory relief for the disposal of hazardous and radioactively contaminated waste under this proposal. One major input that we received from the owners/operators of LLRWDFs during our meeting with them in December 1998 (Ref. 9) is that they want to screen out potentially problematic shipments by testing for chemical constituents. They also want to ensure that the exempted wastes meet the LDR treatment standards and other conditions for exemption proposed today. The notification procedure would allow them to protect their facilities from non-compliant wastes.

Secondly, we are requiring that the generator record the shipment number, from block number 5 of NRC's Uniform Low-Level Radioactive Waste Manifest Form 540, of a radioactive waste shipment that contains RCRA-exempted mixed waste on the notification letter to the LLRWDF receiving the RCRA-exempted waste. We want to provide the LLRWDFs and any regulatory agency a method of identifying, if necessary, a batch of LLW shipment that contained or contains RCRA-exempted waste. After meeting LDR treatment standards, a RCRA-exempted mixed waste would be managed as a radioactive waste. Therefore, without proper documentation, it would not be possible to identify, when necessary, whether a given radioactive waste transported to a LLRWDF contained the RCRA-exempted waste. We believe this identification is necessary to facilitate any actions regarding the RCRA-exempted waste at LLRWDF.

3. What Are the Conditions for Manifesting and Transporting the Exempted Waste?

a. *Why is it appropriate to manifest and transport the RCRA-exempted mixed waste only according to NRC, or an Agreement State's, manifest and transportation requirements?*

We are proposing that only NRC or Agreement State's manifest and transportation requirements be followed for the shipment of the exempted waste. We are proposing to conditionally exempt LLMW or eligible NARM which meets the LDR treatment standards from RCRA hazardous waste manifest and transportation requirements because we believe transportation of this waste according to the requirements for transporting a low level radioactive waste is protective of human health and the environment.

The waste first must be treated to meet LDR treatment standards before it is exempted. During treatment most of the organics in the waste will have been destroyed and the metals stabilized. The LDR treatment standards compliant waste would also no long exhibit any of the ignitible, reactive, and corrosive characteristics. Thus, we believe that the packaging and transportation requirements for a radioactive waste would be adequately protective for the transportation of a waste meeting LDR treatment standards. The Department of Transportation (DOT) supports this assessment. NRC or Agreement State's transportation regulations for low level radioactive waste incorporate the DOT requirements for transporting radioactive material. The DOT's Hazardous Material Regulations (HMR; 49 CFR 100–199) contain requirements for the transportation of hazardous materials. This regulation include packaging, labeling, documentation, placarding, and other requirements. The HMR contain criteria for 9 hazardous classes, some of which are subdivided into divisions. Hazardous materials subject to the HMR, must at least be packaged in strong tight containers that can survive transportation. Performance-oriented packaging is usually required for most hazardous materials. In our discussion with the DOT, they agree that when the RCRA component has been treated thus removing the flammable, corrosive, and reactive properties, then the radioactive waste component would be the primary hazard present and the waste would be shipped accordingly. Therefore, we believe the transportation of the LDR treatment standards compliant waste according to the requirements for radioactive material is appropriate.

We also believe the NRC or Agreement State's manifest requirements for low level waste satisfy the tracking needs for the RCRA exempted waste and ensure the arrival of the exempted waste at the appropriate LLRWDF. Even though the RCRA exempted waste is not required to be manifested as RCRA hazardous waste, a mechanism is still needed to track the movement of this waste. This is because disposal of the RCRA exempted waste in NRC or Agreement State-licensed LLRWDF is a critical condition of the exemption. We must be able to track this waste from the generator to NRC or Agreement State-licensed LLRWDF.

Since the exempted waste remains subject to NRC or Agreement State's manifest regulations, we conducted a detailed comparison between the RCRA and NRC's manifest regulations for the purpose of tracking the movement of the RCRA exempted waste. (Ref. 12) We determined that NRC's waste tracking requirements are at least as stringent as

the RCRA requirements. Most notably, both the RCRA and NRC manifests were developed to be consistent with the shipping paper requirements of DOT (See 49 CFR 172.200). Therefore, the RCRA and NRC manifests share many basic elements. In addition, both manifest regulations require closed-loop notification and tracking, exception reporting, and mandatory record keeping of manifests. NRC's regulations, however, go beyond RCRA requirements in several areas, such as requiring longer manifest retention times in certain cases and specifying more stringent schedules for generators to investigate shipments for which they have not received the LLRWDF's acknowledgment of receipt. Given these observations, we believe that NRC's requirements for tracking of low-level waste would more than meet our needs to ensure that the exempted waste arrives at NRC or Agreement State-licensed LLRWDF. Therefore, we are not imposing additional RCRA tracking requirements in this proposal.

b. *Why do generators who self-regulate under the AEA have an additional condition to meet?*

We are requiring generators who self-regulate their radioactive waste management activity under the AEA authority, such as DOE, to follow 10 CFR 71, and 49 CFR 100–199 transportation requirements and 10 CFR 20 manifest requirements as an additional condition to claim the exemption. Generators and transporters regulated by NRC, or an Agreement State, and DOT are already required to follow these transportation and manifest regulations. For generators who self-regulate under the AEA, this additional condition would ensure the consistent application of the manifest and transportation requirements for the RCRA-exempted radioactive waste.

Secondly, this condition provides a vehicle for taking enforcement action against a facility who self-regulates under AEA if NRC or DOT manifest and transportation regulations are violated. By self-regulating under AEA, DOE is not subject to NRC, or DOT enforcement authority for the management of radioactive material, although we understand that DOE works with both agencies to resolve issues of concern. We believe, however, that enforcement is an important aspect of this regulation. By establishing transportation and manifest requirements as a condition for generators who self-regulate under AEA, we are providing an external enforcement mechanism for the RCRA-exempted waste that would otherwise not exist. Therefore, facilities like DOE would be subject to RCRA enforcement actions if they violated this condition. We did not place this requirement as a condition for the exemption for generators subject to NRC or DOT regulations because they would be subject to NRC or DOT enforcement actions if they violated NRC or DOT manifest or transportation requirements.

As the exemption is contingent upon waste disposal in a NRC or Agreement State licensed LLRWDF, it is important that a mechanism is in place to track all exempted waste in transit and confirm that the exempted waste arrived at the appropriate disposal facility. We do not believe this condition would impose an unreasonable burden on these facilities, as other generators and transporters are all required to comply with these manifest and transportation requirements. In addition, it is also critical that the mechanism used is enforceable. Therefore, we believe this proposed condition provides these facilities with an opportunity to take advantage of the proposal while bearing a reasonable regulatory burden.

4. Why Must the Exempted Waste Be Disposed Only in a LLRWDF Licensed by NRC in Accordance with 10 CFR 61?

We are proposing that the RCRA-exempted waste be disposed of only in a LLRWDF licensed by NRC or Agreement State in accordance to 10 CFR 61 to ensure the protection of human health and the environment from the disposal of the RCRA-exempted waste at these facilities. This is because our evaluation is based on the review and analysis of LLRWDFs licensed and operated by NRC or Agreement State in accordance to 10 CFR 61.

We limited our evaluation of the LLRWDFs to only those licensed by NRC or Agreement State due to concerns raised by the States. The States were concerned about DOE's self-regulating status under AEA. Under such regulatory framework, state radiation control programs do not have regulatory oversight authority for the RCRA-exempted radioactive waste. The NRC or Agreement State has primary responsibility for exercising regulatory authority over the possession and transfer of radioactive material by commercial entities, and some non-DOE Federal facilities. In contrast, DOE is responsible for regulating its own activities under the AEA. The States are concerned that they would lose control over the management of the RCRA-exempted radioactive waste, and lose enforcement authority once it exits RCRA Subtitle C jurisdiction (see VI. H. for further discussion). In most cases, this proposed regulation would need to be adopted by the States before it can be implemented, so it is necessary to ensure that the States' concerns are addressed. We believe that restricting the disposal of the RCRA-exempted radioactive waste to a NRC or Agreement State licensed LLRWDF would address the States' concern regarding DOE's self-regulating status. This approach would ensure that all RCRA-exempted radioactive waste would remain under an external regulatory framework and enforcement authority. In addition, this approach would not exclude DOE from taking advantage of the transportation and disposal exemption if DOE disposes of its exempted waste in LLRWDFs licensed by NRC or Agreement State. This approach allows us to accommodate DOE's waste while addressing the States' concern.

Alternatively, DOE can consider petitioning the States for developing site-specific, risk-based exemption levels through the site-specific risk-based variance approach, if adopted, discussed in section VI.F.2 of this preamble. A site-specific risk-based variance would enable DOE to work directly with mixed waste authorized States to develop appropriate risk levels and exemption conditions.

In addition, this exemption does not apply to disposal at on-site disposal units at environmental clean up activities sites such as disposal units at Uranium Mill Tailings Remediation and Control Act (UMTRCA) sites and Formerly Utilized Sites Remedial Action Program (FUSRAP) sites. This is because the technical analysis that was conducted for this proposal was based on the LLRWDFs that are designed and operated according to 10 CFR 61 and associated technical guidance documents prepared by NRC. The disposal units at UMTRCA or FUSRAP sites are not subject to 10 CFR 61 requirements and NRC or Agreement State licensing process for LLRWDFs. However, the proposed exemption is applicable to remediation wastes from UMTRCA and FUSRAP activities that are hazardous wastes contaminated with radioactivity, and are disposed at LLRWDFs licensed and operated in accordance to 10 CFR 61. provided that the generators meet all the proposed conditions for exemption.

5. What Is the Purpose of the Records That You are Required To Keep?

The records would provide your RCRA program agency with information during inspections and audits to determine whether you are complying with all of the conditions of the exemption. These records could also be

used in possible enforcement actions. Since the exemption is self-implementing, it is particularly important that you keep all of the required records and make them available to the regulatory agency, when requested.

6. How Is the Public Involved?

a. *What Is the role of the public in the proposed transportation and disposal exemption?*

The public can play an important role under today's proposal. During the rulemaking process, the public will have the opportunity to provide comments on the proposal. We welcome and encourage the public to provide comments on today's proposed rule to help us address their concerns. In addition, the public will also have an opportunity to voice their opinions when a state develops regulations to adopt a final rule. At any time, the public can also participate by bringing to the RCRA program agency's attention any circumstance that they are aware of which might aid oversight authorities in their monitoring and enforcement efforts. Furthermore, the public can request information concerning a particular facility's operational records from a state regulatory agency if they have a reason to believe that mismanagement at a facility may pose a risk to human health or the environment. The public can also bring a citizen suit against a generator for failure to comply with the conditions of the Rule.

b. *How can the public obtain information about the exemption and stay involved?*

We recognize the need to enable communities to become more active participants in local environmental issues by providing easy access to information. As the exemption is self-implementing, we do not see the advantages of notifying the public since there is no formal decision-making opportunity, prior to the exemption, that the public could participate in.

Many State environmental agencies have mechanisms, such as telephone hotlines, printed or electronic media, to keep the public informed and to answer questions about public safety and environmental issues. We believe these established procedures and information repositories are sufficient to keep the public informed of the disposal activities of LLRWDFs, and encourage state environmental agencies to utilize these mechanisms. Depending on the structure of the State program, the State agencies may decide to provide public access to relevant information at the State or local level (for example, public libraries, or fire stations).

F. What is EPA's Site-Specific, Risk-Based Variance Alternative for Disposal?

We are proposing an alternative approach which would be based on site-specific risk modeling. We are proposing this alternative because the States have expressed interest in site specific risk-based exemption levels which are more suitable for an individual disposal site. By using a site-specific risk-based approach, a state can choose to customize and establish the exemption levels for a LLRWDF under consideration based on the specific characteristics of the disposal site. Under this approach, we are proposing that the regulated community work directly with the States in developing the site-specific risk-based exemption levels using the risk target level specified by EPA.

For the transportation and disposal conditional exemption, we are proposing to use the current LDR treatment standards instead of modeling to develop new national risk-based levels. However, under RCRA, we can generally grant exemptions and variances from RCRA requirements, if an alternate practice will not adversely impact human health and the environment.

We are asking for public comments on the approach of a state approved site-specific, risk-based alternative to allow the disposal of hazardous waste contaminated with radioactivity in any LLRWDFs including DOE's LLRWDFs. This approach could be pursued by States, an owner/operator of a LLRWDF (NRC or Agreement State licensee or DOE sites), or a consortium of generators of LLMW or eligible NARM. In pursuing this option, a petitioner must demonstrate that the site-specific risk-based exemption levels are protective of human health and the environment as defined by EPA at the disposal location. In these situations, a site-specific risk-based variance petition developed in consultation with and approved by the State RCRA agency may be a desirable alternative to the conditional exemption proposed today.

When developing the site-specific risk-based levels, the petitioner should account for the following factors:

- Climatological and hydro-geological information;
- Information on hazardous constituents of concern in the LLW, or NARM contaminated waste (the number of constituents can be targeted by restricting the RCRA waste codes);
- Potential human and environmental receptors;
- At a minimum, national risk protection goals identified by EPA;
- Potential routes of exposure (i.e., direct and/or indirect); and
- Potential exposure media:

—Groundwater (at a minimum);
—Air, if disposing of bulk waste instead of containerized waste; and
—Surface water, if groundwater-to-surface water connectivity is a concern.

When developing the site-specific risk-based variance approach, the public participation process found at § 268.44(e) would be necessary to provide an opportunity for the public to understand and comment on the site-specific risk levels. (See 62 FR 64507, Dec. 5, 1997 for additional discussion for public involvement.)

Today, we are soliciting comments on whether the States, the regulated community, or non-NRC or Agreement State licensees (for example, DOE) would be interested in pursuing the development of site-specific risk-based exemption levels. We seek comments on the site-specific risk-based variance approach, and the types of guidance documents needed by EPA for site-specific risk modeling. We also seek comments on whether this approach would be preferred over the proposed conditional exemption.

G . How Did we Conduct our Technical Assessment for the Disposal of Treated Waste at Low-Level Radioactive Waste Disposal Facilities?

Our proposed conditional exemption for disposal relies on the benefit derived from the LDR treatment requirements, and the protection offered by LLRWDFs licensed pursuant to 10 CFR 61. Our evaluation of NRC regulations at 10 CFR 61, NRC technical guidance documents, and NRC or Agreement State licensing requirements for LLRWDFs (see Technical Background Document, Ref. 7) forms the basis of our finding that the NRC or Agreement State disposal requirements per 10 CFR 61, and EPA disposal requirements provide comparable protection for human health and the environment. This finding is based on the following:

- The reduced toxicity and mobility of RCRA hazardous constituents when LLMW or eligible NARM wastes are treated to LDR treatment standards.
- Our analysis of NRC regulation licensing requirements for ''near-surface'' disposal of LLW.
- Protection provided against chemical risks to human health and environment when LLMW or eligible

NARM meets the LDR treatment standards and is disposed of in LLRWDFs subject to 10 CFR 61 regulations and the NRC licensing requirements.

Based on this analysis, we concluded that disposal in a LLRWDF would be protective in lieu of RCRA regulation so long as the waste meets RCRA LDR treatment standards and is disposed at a facility meeting the NRC or Agreement State low-level waste disposal regulations according to 10 CFR 61.

The following sections discuss our evaluation of low-Level waste disposal requirements of LLRWDFs, licensed by NRC, for the disposal of LLMW or eligible NARM that has met RCRA LDR treatment standards. For additional discussion, see the Technical Background Document in the RCRA Docket for this proposal. (Ref. 7)

1. How Did We Assess Low-Level Radioactive Waste Disposal Facilities?

We compared low-level mixed waste disposal of hazardous waste in the RCRA Subtitle C program to disposal at LLRWDFs licensed by NRC or an Agreement State. Hazardous waste under RCRA must first be treated according to the LDR treatment standards before the hazardous waste can be placed or managed on the land, and the treated waste continues to be managed as a hazardous waste.

The suitability of disposal of eligible hazardous waste contaminated by LLW or NARM as part of this technical assessment, relies on waste treatment and the placement of waste in an engineered disposal cell meeting the waste disposal facility performance standards specified under 10 CFR Part 61. Our approach recognizes that compliance with LDR treatment standards is integral to the overall protection scheme developed for disposal of eligible hazardous waste contaminated with NRC or Agreement State-regulated radionuclides. In our technical assessment, we also consider disposal facility siting-engineering design-management-control factors that will provide sufficient protection against chemical risks for eligible hazardous waste contaminated by LLW or NARM meeting RCRA LDR treatment standards. In evaluating risks, we considered whether the NRC requirements (10 CFR Part 61) for low-level waste disposal could meet the same general criteria of protection from chemical hazards as a hazardous waste meeting Subtitle C landfill requirements in 40 CFR Part 264. The technical analyses we conducted between RCRA hazardous and low-level waste landfills considered many practices including the following: siting/location, waste packaging/containerization, landfill engineering design, disposal cell/unit management requirements, post-closure care, and institutional controls.

Numerous possible exposure pathways exist based on the combination of sources, exposure medium, exposure routes, and receptor types. For this analysis, we evaluated many possible exposure combinations, selecting the most plausible ones (for example, ground water)based on unit, media, and exposure combinations (landfill ⇻ ground water ⇻ drinking water) and eliminated other pathways based on waste form, unit, and management for example, the least plausible ones (landfill ⇻ overland ⇻ human ingestion).

The proposed requirement of complying with LDR treatment standards and disposal of waste in low-level radioactive waste landfills licensed by NRC or Agreement State were the main factors leading to the elimination of all but groundwater pathways for human exposure. Under the LDR requirements, hazardous waste must meet constituent-based concentrations or technology standards. These requirements result in either reduced constituent concentration, toxicity, and mobility. We believe that the RCRA LDR treatment standards for LLMW or eligible NARM waste and the NRC or Agreement State requirements for LLW disposal including the limit on liquid content of LLW disposal in LLRWDFs, chemical compatibility requirements for disposal, and cover system minimizes the possibility of leaching, volatilization, and gaseous diffusion. In addition, containerization of low-level waste (the waste form and structural integrity requirement of NRC or Agreement State) inhibits leachate generation, particle air dispersion, and run on-runoff from landfill. Also, NRC or Agreement State siting requirements restrict siting of disposal facilities at locations where presence of onsite water bodies and off-site groundwater and surface water connectivity would be of concern.

2. What Was the Technical Assessment we Conducted?

a. *Which low level waste disposal facilities were considered for this analysis?*

Our technical assessment analyzed five disposal facilities under NRC or Agreement State or Agreement State regulation that could be candidates for accepting LLMW or eligible NARM which meets the LDR treatment standards:

- The Chem-Nuclear Systems disposal site in Barnwell, South Carolina (available to all States except North Carolina and those belonging to the Northwest and Rocky Mountain Compacts).
- The U.S. Ecology disposal site in Richland, Washington (available to States in Northwest Compact and Rocky Mountain Compact).
- The Envirocare disposal facility in Clive, Utah (commercial facility not belonging to any Low-Level Waste Compact).
- The U.S. Ecology disposal facility in Ward Valley, California (future site for states in Southwest Compact).
- The Hudspeth County, TX facility in Sierra Blanca, Texas (future site for Texas Compact).
- The disposal status at the last two facilities is currently uncertain. However, as part of our technical assessment, we evaluated them along with the three existing licensed low-level waste disposal facilities.

b. *How were the sites evaluated?*

We evaluated these sites using technical and administrative criteria. The administrative criteria include NRC regulations, guidance, and actual license conditions for site operation and management. The technical portion of the analysis considered climatological, geological, and soil properties. In addition to the site environmental properties, they were also evaluated for siting, landfill unit engineering and construction criteria, closure, and institutional post closure controls (Ref. 7).

i. Are the locational requirements comparable between EPA and NRC regulations?

The locational requirements between RCRA and NRC are generally comparable, with NRC being more restrictive in specific areas. Both programs have very similar restrictions for seismic areas and flood plains. The NRC also bans location of disposal facilities in environmentally sensitive locations, such as wetlands and coastal high hazard areas (10 CFR 61.50(a)(5)). The NRC does mandate restrictions for ground water surface water connectivity on-site and potential restrictions on off-site surface water impact from either ground water connectivity or overland mechanisms (10 CFR 61.50(a)(8)). The NRC also ensures that the disposal facility should not exploit natural resources that would result in not meeting performance objective (for example, potable ground water). The NRC required performance analysis of the disposal site for radiation hazards

factors in: presence of a receptor, duration of transport, and dose to the receptor. The NRC also requires the ability to characterize, monitor, and model the facility (10 CFR 61.50(a)(2)) leading to avoid siting of a disposal facility in areas of complex subsurface geology (e.g. active karst or fractured rock).

ii. Are the treatment and liner/container requirements comparable between EPA and NRC?

In general, the treatment and container requirements are comparable between RCRA and NRC. LLW that is Class A waste must be stabilized according to 10 CFR 61.56(b). NRC also requires that the Class A waste be treated to reduce the potential hazards from the non-radiological constituents to the maximum extent practicable (10 CFR 61.56(a)(8)). These requirements are similar to RCRA hazardous waste treatment requirements applicable to some hazardous waste streams (for example, metal-containing waste, and macro/micro encapsulated debris). Also, as noted earlier, RCRA requires that hazardous waste be treated to LDR treatment standards before the hazardous waste can be landfilled. Both NRC and EPA restrict the liquid content of the waste destined for disposal in landfills. The NRC restricts the free liquid contents to 1% by volume or less. The EPA regulations require use of a specified test showing that under the specified pressure, there is no visible sign of liquid release.

In some instances, the NRC is more restrictive by requiring disposal of waste as containerized waste. NRC regulations require that waste be packaged such that waste form and structural integrity be maintained until the Class A radionuclides decay. However, except for liquid waste disposal, EPA does not require containerization of waste. NRC container requirements require that steel drums or high-integrity containers (HICs) be used to store and dispose LLW and must meet the American Society of Testing Methods (ASTM) performance requirements related to, among other things, structural integrity and resistance to corrosion. In addition to minimizing contact with water, NRC requires disposal of a containerized waste in a disposal cell. RCRA does not require disposal of hazardous waste as containerized waste. However, RCRA requires that landfills be constructed with a double liner and leachate system that at least include a 3-foot thick (91cm) 1×10^{-7} permeability lower liner soil component, and requires that the cover be no more permeable than the landfill's liner system. These RCRA requirements would likely achieve the purpose of the NRC containerization requirements to prevent contact between waste and water and to reduce the potential generation of waste leachate.

iii. Are the landfill design requirements comparable between EPA and NRC regulations?

EPA and NRC take different approaches to landfill design. While EPA relies on prescriptive regulations for cover and liner design and construction, NRC relies heavily on the performance requirements of its cover system, containerization, and environmental setting. The NRC mandate requires that the engineered landfill design system integrates both the site properties (climate, soil geology) along with the performance of the cover system. This integration grants flexibility to the final engineering design, resulting in site-specific landfill unit designs. The integrated disposal systems might include concrete vaults (especially in humid environments of the country—for example, Chem-Nuclear facility at Barnwell, SC) which have a thick cover that might include geo-materials or even a liner. Overall, our analyses indicated a grouping of the cover systems by their performance and that the Subtitle C and LLRWDF engineered systems are comparable (Ref. 7).

NRC requires that the landfill be designed to limit human exposure to a specified level of radioactivity. Unlike RCRA, NRC does not set detailed design specifications for liners, covers, or monitoring in order to prevent releases to groundwater. Instead, AEA landfills are designed to provide assurance that concentrations of radioactive material which may be released to ground water, surface water, air, soil, plants, or animals must not result in exposures to humans above specified health-based levels (10 CFR 61.41). NRC has landfill performance requirements which include that the landfill must be designed to limit human exposure to a specified level of radioactivity and intrusion by humans and animals (10 CFR 61.14(b)). Unlike RCRA, NRC does not set detailed design specifications for liners, covers or monitoring in order to detect and mitigate releases to groundwater. Instead, LLRWDFs are designed to provide assurance that concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants or animals must not result in exposures to humans above specified health-based levels (10 CFR 61.41).

RCRA has certain minimum technical design requirements for landfill covers and liners. These requirements were established to help ensure that disposal requirements of hazardous wastes would limit potential human exposure to hazardous constituents and provide for protection of human health and the environment (3004(a)). For example, RCRA requires that the liner system be composed of an upper liner component such as a geomembrane, a 3 foot thick (91cm) 1×10^{-7} permeability lower liner soil component, and a double leachate collection systems between these liners (40 CFR 264.301(c)), and that the cover be no more permeable than the landfill's liner system (40 CFR 264.310(a)(5)). Because the cover can be no more permeable than the liner, RCRA requires that the cover will at least be of a 3-foot thick layer with 1×10^{-7} permeability.

Some of the chemical constituents in LLMW or eligible NARM could have physical/chemical properties indicating a high potential for mobility in the subsurface or in groundwater. While this situation is theoretically possible, our analysis indicates that LDR requirements and NRC waste disposal requirements (and NRC guidance) for minimizing water infiltration through the cap and contact with the waste (10 CFR 61.50(a)(4), 10 CFR 61.51(a)(4)) will prevent significant releases of chemical constituents from the waste into the groundwater and thus provide for sufficient protection of human health and the environment. The protection of groundwater against chemical releases at LLRWDFs through requirements of this proposed rulemaking is further described below in section v.

iv. How do institutional controls minimize long-term risks?

Post-closure care under RCRA regulations can last for 30 years or more, during which time the ownership of the property remains in private hands. After the post-closure period, the site is available for redevelopment. Under AEA, facility maintains active care for up to 100 years and the facility is in governmental control. The longer active institutional control under AEA should result in better maintenance of the facility and governmental control is a source of long-term control. In some states (for example, New York,) RCRA post closure and financial assurance are required for up to 100 years, much like that required under AEA.

The post-closure monitoring requirements differ between NRC and EPA. RCRA requires that post-closure groundwater monitoring be conducted at all RCRA landfills to assess the potential release of chemical

constituents from the landfill, and that groundwater monitoring be able to allow for the detection of chemical contamination at the point where the constituents could migrate from the landfill to the hydraulically down gradient limit of the landfill which extends down into the uppermost aquifer under the landfill (40 CFR 264.95, 264.97(a)(3)301(c)). NRC also requires that groundwater monitoring be conducted to allow for early detection and mitigation of radiological contamination. However, the regulations are flexible regarding the location of ground water monitoring wells and the extent of the buffer zone surrounding the unit (10 CFR 61.12(b) and 10 CFR 61.53(c)). In practice, ground water monitoring wells are located throughout the facility and not only at the property boundary. The number and exact locations of monitoring wells might not be the same as specified in RCRA (10 CFR 264.95(a)), but they are located in a manner allowing early detection of radionuclides release and appropriate mitigation to provide sufficient protection against contamination of groundwater.

Because the NRC monitoring requirements may only require analyses for radiological constituents (and not for chemical constituents), releases of chemical constituents may not be detected (on-site or off-site). If a joint release of radiological and chemical contamination occurs from an LLRWDF into the groundwater, by the time the radiological release is detected, the chemical release may have traveled farther and be beyond the site boundary, if the chemical constituents are more mobile in the subsurface environment than the radiological constituents. While these situations are theoretically possible, we concluded that the various NRC waste disposal requirements, coupled with LDR requirements would minimize releases of chemical constituents from the waste into the groundwater and thus provide for protection of human health and the environment. The protection of groundwater against chemical releases at LLRWDFs through requirements of this proposed rulemaking is further described below in section v.

v. How is the protection of ground water against chemical release at LLRWDFs addressed in this proposal?

Low-level radioactive waste disposal facilities licensed by NRC or Agreement States are not required to do groundwater monitoring for chemical constituents. These facilities, however, require monitoring of groundwater for release of radionuclides, must report any releases to regulatory agencies, and take action to clean up such releases if of concern.

As discussed above in sections I–iv, low-level radioactive waste disposal facility siting, design, operation and closure are subject to requirements comparable to those for RCRA hazardous waste disposal facilities. Some hazardous waste disposal requirements are more specific than the low-level waste disposal requirements for the potential release of chemical constituents. For example, under RCRA, a double liner and leachate collection system, groundwater monitoring for chemical release, corrective action, and financial responsibility is necessary for hazardous waste disposal. These requirements are not found in NRC regulations. NRC regulations, however, require ground water monitoring, corrective measures, and financial assurance for the disposal of radioactive waste. NRC's facility siting criteria and waste containerization restrictions provide similar outcomes for waste management compared with EPA's requirements for a double liner and leachate collection based on our discussions with NRC and Agreement States. Also, if the radiation hazard becomes a groundwater concern, then the licensed facility must take corrective measures during the operating life of the facility and closure and post-closure care periods. In addition, the disposal facility must provide funds to the regulatory agency overseeing operations of the facility to State to address such concerns once the State becomes responsible for the health and environmental safety at the facility.

In certain instances, 10 CFR Part 61 requirements are stricter (for example, minimizing water/waste contact) thus reducing potential for generation of leachate. Additionally, NRC LLW disposal regulations require that the waste be processed into a form which satisfies the detailed waste characteristics and waste form criteria specified under 10 CFR 61. At a minimum, according to 10 CFR 61.56(a), all wastes disposed at LLRWDFs must be processed into a solid form or packaged in absorbent material ensuring that liquid content of the low-level waste is less than 1.0% by volume found in 10 CFR 61.56(b)(2). A series of technical requirements for these Class B or C LLW, including compressive strength, leach resistance, biodegradation resistance and immersion testing, is found in the NRC Waste Form Technical Position, Revision 1 (January 24, 1991).

We have conducted technical analyses to determine the possibility of a chemical release at the LLRWDFs. We have also conducted a comparison between the drinking water standards and the LDR treatment standards (that is, UTS levels) to determine the potential impact to ground water in the event of a chemical release. Our finding from both analyses indicates that the potential for a chemical release causing a threat to the ground water is not significant. The analysis we conducted was of the screening nature and not all-inclusive for chemical constituents. The analysis was developed for the approximately 90 chemical constituents known to be present in LLMW or eligible NARM waste based on our evaluation of the industry-provided data (Ref. 10). The information is further limited to chemical constituents where values exist for MCL and LDR treatment standards. From the list of 90 MW constituents, 66 have values for MCL and 48 have values for UTS. The constituents lacking UTS values are predominantly pesticides, but also include some chlorinated solvents and inorganics (Ref. 7). We used dilution-attenuation factors (DAFs) to allow for the comparing of waste treatment levels to ground water drinking values. The use of DAFs reflect subsurface transport (for example, advection and dispersion) and fate (for example, sorption on solids and precipitation) phenomena. DAFs were available for 44 of the constituents, with 23 originating from the TC rule and the rest coming from HWIR95 proposal. We used a DAF of 100 for the TC constituents and nationally based values for non-TC constituents from other rulemaking efforts (TC Rule 55 FR 22684, June 1, 1990). We believe that the waste analysis sample population is representative of the mixed waste universe, as identified in the nuclear power industry-provided data , and represents the effectiveness of LDR treatment with regard to the drinking water MCL benchmark. Even though the analysis is not inclusive for all chemicals, the treatment for an identified chemical (for example, incineration of benzene) would be similarly effective for another similar constituent (styrene).

A critical exemption condition under this proposal requires that the LDR treatment standards are met. This requirement will reduce the chemical contents in the waste to a fairly low level. Once disposed, the likelihood of the chemical constituents to leach out to the ground water would be substantially reduced due to the protection provided by treatment and the disposal system.

First, we calculated what the potential concentrations would be in leachate released from LDR treatment standard compliant hazardous waste contaminated by LLW or NARM at LLRWDFs licensed by the NRC or an Agreement State, and assessed what the leachate concentrations would be at receptor wells in the vicinity of these LLRWDFs. We then compared the drinking water standards with the leachate concentrations which we calculated at these receptor wells, and concluded that the potential threat to drinking water would be very low, if any.

Our comparison between the drinking water standard and the leachate concentrations which we calculated for all constituents shows that the two levels compare well (for 75% of 44 constituents the ratio is <1) (Ref. 7). For eight out of 44, the ratio is less than 10, for four constituents (benzo(a)pyrene, ethylene dibromide, hexachlorobenzene, and dioxin), it is greater than 10 and in the case of dibromochloropropane, it is greater than 10, but less than 200. However, based on the mixed waste treatment practices and the available waste volume data (with the LLMW generation rate of 108,000 cubic feet per year), we believe that these constituents with a ratio of greater than 1, are not generally present in these LLMW, and if present the waste volumes are small compared to the quantities of low-level waste disposed of in a disposal cell at LLRWDFs (Ref.7). Furthermore, generally, the volume of the containerized, exempted (solids only) waste disposed at these LLRWDFs licensed by NRC is expected to be quite small relative to the total quantities of containerized LLW that would be disposed in disposal cells at these facilities. (Ref: 7). Therefore, we believe any potential release would be minor.

We evaluated NRC's LLRWDF siting, disposal unit engineering design, containerization requirement, and post-closure care practices. NRC siting regulations require that the disposal site provides long term stability and waste isolation. Final cover requires capping of a disposal unit such that infiltration of rain water and contact of waste with infiltrated water is minimal. The final cover system, consisting of compacted clay, high density polyethylene layer, and a vegetative layer would reduce entry of water into the disposal unit. The requirement for containerization of the waste also controls the potential for waste/liquid contact and subsequent leachate production. In addition, the landfill bottom design promotes short liquid/waste residence time. Thus, the contact of liquid with the waste would be minimal and that would act to minimize any hazardous constituent concentration in the leachate (and hydraulic head—a function of the presence of a water column and its thickness). These requirements significantly reduce the likelihood for potential leachate generation at LLRWDFs licensed by the NRC or Agreement States.

These findings and the technical analysis discussed above led us to conclude that in the unlikely event of a chemical release, subsequent groundwater contamination is not likely to be of significant concern. To further verify our analyses, we discussed with state regulators, in states where the LLRWDFs are located, regarding any past releases from the existing LLRWDFs. Based on our investigation, we understand that there have been no releases of radionuclides, above the regulatory limits, detected in the ground water at offsite, commercial LLRWDFs since 10 CFR 61 has been promulgated in 1982. The LLRWDFs that were operational at that time were required to be upgraded to meet these regulations. Since then, the two low-level waste disposal facilities at Richland, WA and Barnwell, SC (that were operating before the promulgation of the NRC regulations at 10 CFR 61) have been retrofitted, and their licenses have been amended pursuant to 10 CFR 61 required standards. In conclusion, we believe that the disposal of LLMW, meeting LDR treatment standards, in NRC or Agreement State licensed LLRWDFs will not pose a threat to ground water and cause concern for health risks. We recognize that some members of the public may still be concerned about potential chemical releases at LLRWDFs. Therefore, we are soliciting comments on whether we need to consider, as a condition for the exemption, groundwater monitoring for chemical releases. We are also requesting groundwater monitoring data from LLRWDFs.

vi. Why would corrective measures and financial responsibility provisions beyond those under 10 CFR 61 be unnecessary?

We believe NRC's waste form requirements and low-level waste disposal cell design and capping requirements in combination with the condition that the waste meet LDR treatment standards will minimize water entry, leachate generation, and releases. Also, NRC requires corrective measures to address groundwater contamination if of concern. In the event of a release, based on our discussion with an Agreement State, we understand that both the radioactive and chemical components would be remediated because they are mixed together. This is especially true if the concentrations exceed regulatory limits such as safe drinking water levels or other alternate levels. Therefore, we believe that the Agreement States would also require a facility during active life, closure, and post closure phase to be responsive to releases and subsequent health concerns related to chemical constituents. Hence, a ''corrective action'' requirement similar to that required under RCRA Subtitle C is not necessary.

With regard to remediation, NRC's requirements for reporting and taking corrective measures for radiological releases (including mixed waste for the hazardous constituents) specify that a NRC-licensed facility respond to and institute remedial action for a release of radioactive waste. Also, in 10 CFR 61.53(b) a LLRWDF is required to have plans for taking corrective measures. When promulgating the exemption from RCRA Subtitle C for petroleum contaminated media and debris, EPA determined that subjecting contaminated media to RCRA C-based corrective action was not appropriate or necessary because an alternative regulatory program (RCRA Subtitle I) would provide the requisite degree of protection to human health and the environment (55 FR 11836). Our proposal to exempt LLRWDFs that accept exempted waste for disposal from RCRA corrective action requirements is similar to the petroleum contaminated media exemption. Based on our review of NRC corrective requirements for potential radiological releases, including mixed waste, we believe that those NRC requirements for addressing releases associated with mixed waste are adequate. The likelihood of a potential chemical release after the disposal of relatively small quantities of RCRA-exempted waste (especially containing hazardous constituents at or below the LDR treatment levels) of very low concentration is negligible (based on our UTS/MCL comparison) (Ref. 7). We, therefore, would expect imposition of RCRA Subtitle C-type corrective action to be unnecessary.

With regard to financial assurance, the LLRWDFs are financially responsible for clean up of groundwater during operations, if it poses a health threat. In addition, 10 CFR 61 requires LLRWDFs to establish financial assurance that will provide funding for closure and post-closure care. The NRC or Agreement States are unlikely to require clean up of radionuclides alone

in the event of mixed waste contamination. Therefore, we do not believe that additional RCRA-like financial assurance is necessary to address the unlikely event of chemical contamination of groundwater resulting from disposal of the exempted waste at LLRWDFs.

In addition to the NRC-required corrective measures pursued by the LLRWDF or the Agreement State, we retain our broad RCRA authority, specifically, under RCRA 7003. Under this authority, we can bring suit and require the responsible party(ies) to take necessary action. And, under 40 CFR 302.4, we have independent response authority under CERCLA, if a release of a hazardous substance is in excess of a ''reportable quantity.''

We request comment on whether for any reason under this conditional exemption, we should require LLRWDFs to provide RCRA-like financial assurance for cleanup of RCRA hazardous constituents.

vii. What are the uncertainties of our technical analysis?

This section identifies the primary sources of uncertainty associated with the comparative and technical analysis described above, and qualitatively describes how each may influence the results of these analyses. Sources of uncertainty identified in our analyses include the following:

- Much of the data that we used to assess the protectiveness of radioactive waste disposal regulations of NRC and EPA regulations for hazardous waste landfills were not directly measured. For example, we relied on existing reports and waste surveys; no independent field study supported the technical work. Some of the most important and sensitive parameters which we considered in our analyses include those that describe waste composition; waste management practices; and site characteristics. While not specifically addressed in our technical approach, the parameters and exposures considered include physiologic and behavioral exposure characteristics of the receptors; the physical, chemical, and biochemical properties of the hazardous waste contaminants; and toxicological effects indirectly factored in using MCL and DAF benchmarks.
- EPA did not have chemical constituent groundwater monitoring data from wells surrounding LLRWDFs. This information would help us to assess whether chemical constituent releases have occurred at these facilities. While information was available on radioactive constituents, the lack of chemical data results in the inability to evaluate the relationship for fate and transport and the potential risk to receptors for all possible constituent combinations. For example, chemical constituents present could be either more or less mobile than the radioactive constituents present, resulting in either an over-or underestimation of chemical hazards.
- LDR treatment to ground water protectiveness was of the screening nature and not all-inclusive. The information is limited to chemical constituents where values exist for MCL, LDR treatment standards, and DAFs. The gaps in this data for where an MCL, UTS, or DAF does not exist may result in either an overestimation or underestimation of the potential chemical hazard to receptors.
- We did not conduct a quantitative risk-based analysis geared to the sites where disposal may occur. We also did not quantitatively estimate the risk of developing cancer from the potential exposure to chemical contaminants in the waste. The lack of a quantitative risk analysis leads to sources of uncertainty in assessing the most sensitive potential toxicological effects, exposure routes, and constituents of concern within the waste. While our analysis did factor in site-specific data, we did not address future siting of LLRWDFs because of the difficulty of siting new facilities as seen in recent site rejections (for example, Ward Valley in CA, Nebraska site). As a result, our technical analyses might overestimate or underestimate the potential chemical hazard to receptors.
- The technical analysis did not specifically assess risks to sensitive subpopulations and environments. The likelihood that landfills are located in certain environmental areas where constituents might move significantly with groundwater is uncertain. The waste treatment, packaging, waste form requirement, and the existence of physicochemical limitations (e.g., interactions between contaminants and aquifer material), biological and chemical degradability of other constituents that may be present (e.g., sandy or other porous soils), soil organic matter and clay content, soil exchange capacity, dissolved organics or organic acids in the groundwater, competing cations, changes in soil environmental conditions such as organic waste matrix, pH, redox potential or soil solution composition over time, and other physical and chemical characteristics of the ground water and geological medium, might significantly increase/decrease the mobility of chemical constituents in groundwater in the short term (seasonal variation) as well as long term (for example 10,000 years).
- The likelihood that the NRC licensing process will apply more stringent groundwater protection requirements and criteria to mitigate radiological releases to the groundwater is given. With regard to mitigating chemical releases to the groundwater, if any, by the licensing agency we understand that the licensing agency would require remediation of radioactive material in groundwater and work with any other regulatory authorities to ensure that non-radioactive material contamination is also addressed.
- The extent to which State requirements will address some of the key landfill design factors discussed above is uncertain.

There are potentially significant uncertainties regarding whether and how exposure will occur. Also, our comparison between land disposal regulations for NRC and EPA presents simplifications of reality. The different approaches used by the two programs lead to a certain degree of uncertainty in making the comparative analyses used in this study. In addition, the variations in site-specific conditions and implementation of the permit/license are virtually impossible to completely account for when determining protection of human health and the environment. The comparison was intended to approximate real-world conditions and processes, and their relationships. Because of the nature of our technical approach, the analysis we have pursued for this proposal did not include all parameters or equations commonly seen in a detailed risk-based modeling approach. Consequently, the technical approach was based on various assumptions and simplifications, and as a whole could result in either an overestimation or underestimation of the potential comparative protectiveness between the EPA hazardous waste and NRC LLW disposal systems.

3. What Did We Conclude From our Technical Analyses?

We evaluated NRC's LLRWDF siting, disposal unit engineering design, containerization requirement, and post-closure care practices. We found that as a whole these attributes provide comparable protection to that provided by a RCRA hazardous waste landfill. NRC siting regulations require that the disposal site provides long term stability and waste isolation. Final cover requires capping of a disposal unit such that infiltration of rain water and contact of waste with infiltrated water is minimal.

The final cover system, consisting of compacted clay, high density polyethylene layer, and an evapotranspiration (that is, evaporation of water from top layers of cover and water removal by vegetation used as an integral part of the final cover) rate greater than the rate of precipitation would all but eliminate the entry of water into the disposal unit. The requirement for containerization of the waste also limits the potential for waste/liquid contact and subsequent leachate production. In addition, the landfill bottom design promotes short liquid/waste residence time; thus, the contact of liquid with the waste would be minimal, minimizing hazardous constituent concentration in the leachate and hydraulic head (a function of the presence of a water column and its thickness). At the NRC or Agreement State regulated facilities, the likelihood of water and waste contact is highly unlikely and therefore, potential for leachate generation is significantly reduced, thus mitigating the need for a liner and leachate collection. We found many similarities between the two programs (Ref. 7):

- Locational requirements for siting of disposal units;
- Prohibition on the disposal of free liquids;
- Treatment of waste to reduce health hazards;
- Disposal of waste in an engineered landfill; and
- Extended period of institutional control.

There were a few differences between the two programs:

- Hazardous waste landfills must have a liner and leachate collection, while AEA only requires leachate collection;
- Most low-level waste disposal can only occur as containerized waste (in containers with a structural integrity of 100–300 years), while hazardous waste disposal does not specify containers, although the liner could be viewed as a form of containerization;
- Since hazardous waste disposal regulations do not require containerization of solid waste, the potential for particulate emissions exists; and
- NRC-requires institutional control for a minimum of one hundred years under State control; while EPA-requires post closure care for 30 years.

In addition, the adoption and enforcement of both the EPA and NRC regulations by the States tends to make the State programs under both EPA and NRC more protective than the Federal requirements. States generally consider site-specific concerns (such as sensitive populations or the local economy) in the design of their regulations and the implementation of the state programs.

States may also consider site-specific concerns such as protection of surface water, wetlands or endangered species. Thus, a State program may be more stringent than the RCRA federal program or less stringent (depending on the site performance assessment) as allowed under the NRC. As part of the State-implemented conditional exemption, a State may require groundwater monitoring for potential chemical releases or inspect the LLRWDF-generated groundwater monitoring data for detecting releases of radionuclides and use this information as a surrogate or indicator for releases of hazardous constituents with similar fate and transport characteristics.

In conclusion, even though EPA and NRC waste disposal regulations follow different approaches, we believe that both ultimately achieve a high level of protection.

H. Key Stakeholder Issue

In 1995, we published in the **Federal Register**, a notice of proposed rulemaking (referred to as the HWIR95), which, among other things, requested comments on several options for conditional exemption from RCRA Subtitle C management requirements (60 FR 66344; December 21, 1995). One option we suggested (60 FR 66344, 66400–66401) would have exempted mixed waste from Subtitle C hazardous waste disposal regulations if they were treated to meet risk-based chemical constituent concentration levels and were managed in disposal facilities subject to controls imposed under the AEA. In response to the HWIR95 proposal, the Department of Energy (DOE) submitted alternative proposals for our consideration, which would have allowed certain treated mixed wastes generated by DOE to be conditionally exempted from RCRA Subtitle C hazardous waste disposal requirements, if such mixed wastes were disposed in a DOE self-regulated LLRWDF. Several State RCRA Agencies and Attorneys' General expressed concern over DOE's proposals, and also were opposed extending the HWIR95 risk-based exit levels to DOE mixed waste (see public comment in RCRA docket in response to the HWIR95 proposal-Ref. 15). In particular, States were concerned that they would no longer have regulatory jurisdiction over DOE's RCRA-exempted radioactive waste once the wastes are disposed in DOE's self-regulated LLRWDF. We encouraged DOE to work with the States to resolve this issue, since States would be the implementing agencies of a proposed RCRA exemption in most cases. The States and DOE held discussions over a period of one year without reaching a resolution. DOE has subsequently suspended the alternative proposals it had submitted. DOE has also been working with the States to discuss its LLMW disposal options and plan LLMW disposal capacities. The planning of DOE's LLMW disposal facilities would eventually provide DOE with relief to its LLMW disposal dilemma.

Given that the issue between the States and DOE was not resolved, we tried in this proposal to provide some regulatory relief to DOE for its LLMW while respecting the States' need to retain oversight of DOE generated LLMW. We are, therefore, proposing to allow the exemption to be applicable to all generators of LLMW or eligible NARM including DOE. However, we limited the disposal of the RCRA-exempted waste to only those LLRWDFs licensed and regulated by NRC or Agreement State. In this way, DOE could utilize the conditional exemption for disposal while the NRC or Agreement State radioactive material control programs would retain the oversight of the RCRA-exempted waste. In addition, commercial LLRWDFs have indicated that they would be willing to consider accepting DOE conditionally exempt waste for disposal, if such acceptance does not conflict with their agreement with the State low-level waste compacts.

VII. Regulatory Impacts

We anticipate that implementation of this rule will result in incremental benefits (from cost savings and risk reductions) and some incremental costs. These costs are expected to be much smaller than the overall benefits of the rule. (Ref. 14 and 17.)

We have based our assessment on the best data available; full references and details are available in the Regulatory Impact Analysis which accompanies today's proposal. We have also assumed that generators will be willing and able to dispose of their waste in LLRWDFs, within the scope of existing limitations on capacity and acceptance criteria.

Significant uncertainties make it unusually difficult to estimate the impacts of this rulemaking. In addition to uncertainties about the quantities of LLMW generated in the U.S. there are also questions about the eventual disposition of these wastes. Although this rulemaking creates opportunities for disposal of much of this waste, these opportunities also depend on as-yet undetermined action by State regulatory

agencies, LLRW disposal facilities, and the generators themselves. These uncertainties and assumptions, however, do not affect the Agency's assessment of positive net benefits stemming from this rule; they only affect the magnitude of that net benefit. To the extent that any generators can take advantage of storage or disposal provisions of this proposal, net benefits will accrue.

Sections A and B below provide further detail on benefits and costs associated with this rule; Section C addresses economic impacts. We base assessment of benefits and costs on a comparison of waste management after implementation of this proposal as a final rule compared with waste management in the absence of this rule.

A. What Are the Regulatory Benefits of This Rule?

In 1990, EPA, NRC and the Oak Ridge National Laboratory conducted a survey of commercially generated low-level mixed waste (Ref. 8). A report of the survey findings was published in 1992 under the title: National Profile on Commercially Generated Low-Level Radioactive Mixed Waste. As stated in the Executive Summary ''The * * * objective of the work was to compile a national profile on the volumes, characteristics, and treatability of commercially generated low-level mixed waste * * * by major facility categories * * * [including] academic, industrial, medical, and * * * government facilities and nuclear utilities.'' Based on this research, and site visits in 1998 (see docket to ANPR), we believe that there are a number of LLMW generators, who could benefit from this proposed regulatory relief. Based on the 1992 Study (which was weighted to develop a statistically valid estimate of the nation) we estimated that the national generation rate of mixed waste was 108,000 cubic feet per year and that 4,000 cubic feet of mixed waste was in storage for various reasons. (Ref. 14 and 17.) Nuclear utilities accounted for roughly 10 percent of the total commercially generated LLMW volume in the United States. ''The industrial category was estimated to be the largest generator and accumulator of mixed waste, with over 36% of the generation and nearly 57% of the storage, of the total mixed waste in the United States in 1990.'' (Ref. 8, p. 40). Based on our discussions with the regulated community, we understand that commercial generators of LLMW have taken a number of steps, including pollution prevention, waste minimization, and source reduction (such as using water-based scintillation cocktails as opposed to the solvent-based formulations), to reduce quantities of LLMW they generate. Also, nuclear power plants have instituted steps for controlling the use of organic solvents (for example, establishing procedures to track quantities of organic solvents purchased, used, and left over/discarded). Therefore, despite industrial growth over the intervening years, we believe that the LLMW volumes generated today would not be much different from those reported in 1992. Some federal facilities also generate LLMW. The total volume of LLMW generated annually by DOE facilities far exceeds the volume generated by the commercial sector.

Benefits from this rule may accrue in the following areas:

- Permitting cost savings: Those generators needing RCRA permits only for storage or treatment of their mixed wastes will save these permitting costs and associated corrective action costs.
- Decay in Storage cost savings: The rule would allow facilities to store certain wastes while their radioactivity decays. These wastes could then be treated and disposed as hazardous waste, which is less expensive than LLMW treatment and disposal. EPA estimates aggregate cost savings from these waste streams will be between $800,000 and $2,600,000 per year.
- Other disposal cost savings: This rule would facilitate disposal of wastes in LLRWDFs, possibly saving between $100,000 and $800,000 each year. EPA has not estimated savings resulting from reduced storage costs.
- Other cost savings: Generators of mixed waste and Federal/state RCRA regulating agencies are expected to save administrative burden and costs because of this regulatory relief.
- Risk Reductions: EPA anticipates that generators will take advantage of relaxed storage restrictions to allow certain LLMW to undergo decay in storage. NRC or Agreement State approves this process which allows certain short-lived radionuclides in these wastes to decay. The remaining decayed waste no longer meets the definition of radioactive under the AEA. Since EPA does not expect these wastes to be treated or handled during the radioactive decay process, waste handlers in treatment and transportation will not be exposed to this radioactivity. This decrease in exposure translates to an unquantified risk reduction, attributable to the relaxed RCRA storage restrictions in this proposed rule.

DOE may also save on transportation and disposal costs, to the extent that they choose to meet the conditions for exemption and dispose of wastes in commercial disposal facilities licensed by NRC or an Agreement State. DOE would not gain permitting or storage cost savings, since these regulations do not currently apply to DOE facilities.

B. What Are the Costs of This Rule?

Generators, who are not meeting regulatory requirements for disposal, may incur some increased spending for treatment and disposal relative to their current costs under RCRA hazardous waste management if this rule is implemented, but not relative to costs of meeting existing RCRA Subtitle C regulations. This is because this rule will open up disposal capacity for wastes which currently do not meet the waste acceptance criteria of the existing LLMW disposal facility. Without this rulemaking, these legacy wastes might simply continue to be stored on site indefinitely, leaving the generators in violation of RCRA permit requirements. These generators would incur not only storage costs, but costs associated with being in violation of RCRA.

Generators taking advantage of disposal exemptions will incur costs to meet notification conditions. EPA has not quantitatively estimated costs of compliance with these notification conditions; but expects these costs to be smaller than the administrative cost savings that accrue to generators under this proposed rulemaking.

Under this rule, there will also be some increased costs to EPA and state agencies overseeing management of mixed wastes. We expect these entities to incur costs associated with notification conditions for generators/treaters of LLMW (that meets the LDR treatment standards); sending their waste for disposal at LLRWDFs and related implementation costs. This will result in a small increase in costs for these regulating bureaus. As a whole, costs to EPA and state agencies are likely to be far lower, since these regulatory agencies will have reduced administrative costs as noted in section A above.

C. What Are the Economic Impacts of This Rule?

By allowing LLMW to be disposed as LLW, this rule may have impacts on the national market for disposal of LLW, although we have not specifically modeled these impacts. The larger the volume to be added to the disposal market, the greater the effects are likely to be. The largest volumes of LLMW potentially to be disposed at commercial LLRWDFs are those generated by the Department of Energy, including wastes from site cleanup/remediation activities.

Overall, we expect aggregate economic impacts to be positive for all

LLMW generators and LLW disposal facilities. Some generators may find increased costs for treating and disposing of wastes which were previously stranded on-site; without the rule, these facilities would incur permitting costs, continuing storage costs, and potentially the costs of being in violation of RCRA. The only possible negative impact may fall upon the single mixed waste disposal facility which currently accepts some LLMW for disposal. By allowing LLRWDFs to dispose of the LLMW that meets Land Disposal Restrictions, this rule will introduce some competition into the market for disposal of LLMW. Most of the wastes affected by this proposed rule, however, are unlikely to have been disposed at the existing facility (see the Regulatory Impact Analysis for complete explanation. Ref. 14 and 17).

VIII. State Authorization

As of December 1998, a total of 40 states and one territory were authorized for implementing RCRA mixed waste regulations. In States (and territories) that have not received final authorization to implement the RCRA program, the final rule would apply upon the effective date. Since this rule is not being promulgated under HSWA statutory authority, it would not apply under RCRA in States with final authorization until those States amend their laws and become authorized for it. Moreover, because this rule will likely be considered less stringent than the current RCRA program (since the proposed rulemaking suggests some additional flexibility for disposal or permitting), States will not be required to adopt it.

We, however, encourage States to adopt this conditional exemption. The conditional exemption provides a regulatory enforcement mechanism for States to bring against generators who may be out of compliance with the conditions. Under this regulatory framework, States would retain their regulatory oversight and RCRA enforceability provisions over the non-compliant claimant. A LLMW generator not meeting the conditions for exemption from hazardous waste storage requirements and those for exemption from the definition of hazardous waste when LLMW disposal occurs at LLRWDFs licensed by the NRC or an Agreement State may be subject to the penalties under the RCRA hazardous waste enforcement program.

If States where LLRWDFs licensed by the NRC are located (for example, South Carolina, Utah, and Washington) have concerns regarding post-disposal releases of hazardous constituents in LLMW, these States could address these concerns when adopting this rule. (See Section 3009 of RCRA.) A State may add a requirement for ground water monitoring for potential chemical releases, or use the LLRWDF-generated groundwater monitoring data for release of radionuclides as surrogate or indicator data for releases of hazardous constituents with similar fate and transport characteristics.

IX. Relationship With Other RCRA and Environmental Programs

A. What is the Relationship of This Proposal With Other RCRA Regulatory Programs?

Below, we discuss how this proposed rule would affect other relevant RCRA regulatory programs.

1. Does This Proposal Change How You Determine if a Waste is Hazardous?

No, the proposed rule is a conditional exemption from the RCRA definition of hazardous waste. It does not change the general requirements to determine if a waste is hazardous. Under current RCRA regulations, if you generate a solid waste, you must first determine if it is a hazardous waste as outlined in 40 CFR 262.11, Hazardous Waste Determination. A generator of LLMW must also determine if the waste is excluded from regulation under 40 CFR 261.4, Exclusions. Next, a generator must determine whether the waste meets the regulatory description for a listed hazardous waste in subpart D of part 261, Lists of Hazardous Wastes. If the waste is not a listed hazardous waste, the generator must then determine if the waste exhibits a characteristic defined in subpart C of part 261.

LLMW that meets the LDR definition of non-wastewaters and exhibits toxicity characteristic must be treated to meet the LDR treatment standards and decharacterized to meet the TC regulatory limits at § 261.24 before it can exit RCRA Subtitle C and be disposed of as a nonhazardous solid waste. Under the proposed conditional exemption addressing disposal of LLMW, LLMW that is a TC waste must be treated to meet the LDR treatment standards, but not the TC regulatory limit in instances where the TC limit is lower than the LDR treatment level.

2. Can a LLMW or Eligible NARM be a Non-Hazardous Waste Under this Proposal?

LLMW or eligible NARM meeting the LDR treatment standards in a ''pure untreated form'' (that is, as generated waste) would be a conditionally exempt non-hazardous waste under this proposal. For the waste to maintain a non-hazardous waste status, the generator must meet all the other conditions for exemption proposed today.

3. How Will the RCRA-Exempted Waste Differ From Wastes Delisted per 40 CFR 260.22?

The evaluation criteria used for delisting vary from today's proposal to conditionally exempt LLMW or eligible NARM from the RCRA definition of hazardous waste. In today's proposed conditional exemption the evaluation criteria are national and categorical. This contrasts with the evaluation criteria for delisting which are based upon a designated waste stream and are case specific. In delisting, we evaluate the processes generating a specific waste stream to determine the constituents likely to be present, as well as the potential variability in the waste.

4. Will My Waste Analysis Plan of My RCRA-Permitted TSDF Change?

No, if you are an owner or an operator of RCRA-permitted or interim status TSDF, also licensed by the NRC for managing LLW, and plan to claim a conditional exemption, you remain subject to the waste analysis and waste analysis plan requirements of part 268. DOE treatment facilities treating LLMW to meet the proposed conditions for exemption are also subject to the waste analysis and waste analysis plan requirements of part 268.

If you are not a RCRA-permitted hazardous waste treatment facility and elect to employ the proposed exemption procedures following promulgation of a final LLMW rule, you must submit a RCRA part B permit application.

5. Will the Proposed Rule Change How the RCRA Closure Requirements Apply to My Disposal Facility?

If you're a disposal facility subject to NRC regulations for disposal of LLW and you accept conditionally exempt LLMW the hazardous waste facility closure requirements do not apply. If, however, it has been determined that your disposal unit received RCRA-exempt mixed waste from a generator who has violated the conditions for exemption, the disposal cell where the exempted waste has been placed for permanent disposal may become a RCRA regulated Subtitle C unit subject to the requirements of 40 CFR parts 264 or 265, including closure requirements, until you completed clean closure of the unit or unless all of the wastes in the unit were delisted. You would normally be required to complete closure

activities within 180 days after receiving the final volume of hazardous waste. (See Time Allowed for Closure in 40 CFR 264.113(b) and 265.113(b).) However, RCRA closure requirements would allow you to delay closure of your waste management units, while continuing to receive the RCRA-exempted low-level mixed waste, if you meet certain conditions. (See ''delay of closure'' options at 264.113(d) and 265.113(d).

We believe that the availability of a delay-of-closure option provides much of the flexibility needed to allow for the uninterrupted management of exempt waste, while providing assurance that the protections afforded by the closure regulations for RCRA Subtitle C units, such as evaluation of soil and groundwater at closure, are not lost.

To minimize applicability of RCRA hazardous waste management requirements, owners/operators of a NRC or Agreement State licensed LLRWDF may consider some precautionary measures. For example, you may require LLMW generators to provide you with any documentation (e.g., test results, process knowledge) that the generators have used to make their LDR determination. Alternatively, you may require LLMW generators to provide a representative LLMW sample for independent waste testing and analysis to verify that the waste indeed meets the LDR treatment levels. This would assist you to assure that a LLMW generator has not mis-characterized the waste and/or to document compliance with exemption requirements in the event a RCRA program agency exercises its enforcement authority with regard to your facility.

6. How Does the Conditional Exemption Relate to RCRA Air Emission Standards?

Under this proposal LLMW or eligible NARM meeting LDR treatment standards is not likely to release volatile air emissions. Thus, it would be exempt from RCRA Subtitle C regulations, including the air emission standards. Once a LLMW or eligible NARM is no longer regulated as hazardous, any unit in which the waste is managed (assuming no other hazardous waste management in that unit) is no longer subject to RCRA Subtitle C regulations, including 40 CFR Parts 264 and 265, Subparts AA, BB, and CC.

B. What is the Relationship of this Rule to Other Environmental Programs?

1. How are CERCLA Actions Affected by this Proposal?

The affect of today's proposed regulations on Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) actions depends on whether the waste will be managed on or off the CERCLA site. Off-site disposal of CERCLA remediation waste must comply with all conditions of today's proposal to take advantage of the exemption provided. These wastes must go to a LLRWDF that is in compliance with the 10 CFR Part 61 regulations and is licensed by the NRC or Agreement State.

Management of mixed waste during on-site remediation waste must meet all applicable, or relevant and appropriate requirements of Federal or State environmental laws or justify a waiver from those standards. This proposal requires that the disposal facility be licensed and overseen by the NRC or Agreement State. On-site CERCLA response action must comply with the substantive provisions of environmental regulations and standards, but not the administrative provisions. As such no permit or license is required for on-site activities. In accordance with the National Contingency Plan and the statute, today's proposed regulation is not expected to be an applicable requirement at most CERCLA sites managing LLMW. However, relevant and appropriate determinations are a site-specific determination and these may or may not be deemed relevant and appropriate given site-specific conditions. In general, we expect that most CERCLA sites will meet both the substantive provisions of the RCRA Subtitle C landfill requirements as well as the 10 CFR 61 requirements for a LLRWDF.

2. How Might Clean Air Act Regulations be Affected?

This rule will not affect Clean Air Act regulations. LDR treatment of LLMW or eligible NARM remains subject to the air emission standards applicable to hazardous waste treatments under RCRA.

3. How Might Clean Water Act Regulations be Affected?

This rule will not affect Clean Water Act regulations. Any water discharges from LDR treatment of LLMW or eligible NARM remain subject to water discharge standards applicable to hazardous waste treatment under RCRA.

X. Regulatory Assessment Requirements

A. Executive Order 12866: Determination of Significance

Under Executive Order (E.O.) 12866, (58 FR 51,735 (October 4, 1993)) the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action.'' While this notice of proposed rulemaking establishes few regulatory requirements, it could ultimately result in a rule that would satisfy one or more of the remaining criteria. Therefore, this action is a ''significant regulatory action'' under the terms of E.O. 12866. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

Under the terms of E.O. 12866, EPA is to prepare for any significant regulatory action an assessment of its potential costs and benefits. If that action satisfies the first of the criteria listed above, this assessment must include, to the extent feasible, a quantification of these costs and benefits, the underlying analyses supporting such quantification, and an assessment of the costs and benefits of reasonably feasible alternatives to the planned regulation. This proposed rulemaking is expected to yield net benefits to society, because of reduced waste management and administrative costs for both generators of mixed waste and regulatory agencies, and reduced worker exposures. A summary description of costs and benefits associated with this proposal appears in section VII. An initial regulatory impact analysis has been prepared and is available in the docket for today's proposed rulemaking. EPA is requesting comment on the costs and benefits of any of the possible regulatory changes discussed in this proposed rulemaking, as well as on appropriate methodologies

for assessing them. We would like to hear from States, Tribes, members of the public, and the regulated community.

B. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to the Office of Management and Budget (OMB), in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. For final rules subject to Executive Order 13132, EPA also must submit to OMB a statement from the agency's Federalism Official certifying that EPA has fulfilled the Executive Order's requirements.

This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132, because it will not impose any requirements on States or any other level of government. As explained above, today's proposal would provide regulatory flexibility for generators and treaters of Low Level Mixed Waste by establishing a conditional exemption from RCRA Subtitle C requirements, which States would not be required to adopt. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

C. Executive Order 12898: Environmental Justice

Under Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' as well as through EPA's April 1995, ''Environmental Justice Strategy, OSWER Environmental Justice Task Force Action Agenda Report'' and National Environmental Justice Advisory Council, EPA has undertaken to incorporate environmental justice into its policies and programs. EPA is committed to addressing environmental justice concerns, and is assuming a leadership role in environmental justice initiatives to enhance environmental quality for all residents of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, or income, bears disproportionately high and adverse human health and environmental effects as a result of EPA's policies, programs, and activities.

To address this goal, EPA considered the impacts of this proposed rulemaking on low-income populations and minority populations. EPA believes that due to low estimated waste volumes stored under the storage exemption, any potential risk resulting from this proposal would be very small. In addition, this waste would be stored according to another regulatory authority (NRC) which offers comparable protection. Under the disposal proposal, the exempted waste would be disposed following NRC regulations which provide comparable protection and low risk. The Agency does not currently have data on the demographics of populations surrounding facilities which generate low-level mixed waste that potentially could be affected if today's proposed rule were finalized. However, we believe that the LLMW generators storing the waste and the LLRWDFs do not appear to be concentrated in areas where the minority or the disadvantaged groups reside. Therefore, we believe there would not be disproportionately high and adverse environmental or economic impact on any minority or low-income group, or on any other type of affected community. Any minority group or low-income group affected by alternatives described in this proposed rulemaking has an opportunity to review and comment on the proposal.

D. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rulemaking is not subject to E.O. 13045 because it is not an economically significant rule as defined by E.O. 12866. We do not expect this rule to disproportionately affect children because we do not expect children to be entering LLMW storage areas which are locked and have limited access requirements imposed by NRC. Similarly, disposal facilities must meet NRC regulations for public safety thus reducing the likelihood of exposure of the nearby population including children.

E. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. This order requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, E.O. 13084 requires EPA to develop an effective process that permits elected officials and other representatives of Indian tribal governments ''to provide

meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's proposal does not significantly or uniquely affect the communities of Indian tribal governments. There is no impact to tribal governments as the result of generator's choosing to claim a conditional exemption for storage units containing low-level mixed waste. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

F. The Regulatory Flexibility Act as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996) whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities.

SBREFA amended the Regulatory Flexibility Act (RFA) to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. EPA has examined this proposed rulemaking's potential effects on small entities as required by the Regulatory Flexibility Act and has determined that this action will not have a significant economic impact on a substantial number of small entities. The overall economic effect of this regulation has been determined to be a net savings to all regulated entities who choose to avail themselves of a conditional exemption for storage or disposal of the mixed wastes they generate. Since this rule will not impose additional costs on any entities, I hereby certify that this rule will not have a significant economic impact on a substantial number of small entities. This rule, therefore, does not require a regulatory flexibility analysis.

G. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under § 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, § 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of § 205 do not apply when they are inconsistent with applicable law. Moreover, § 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under § 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements. The UMRA excludes from the definition of ''Federal private sector mandate'' duties that arise from participation in a voluntary federal program and also generally excludes from the definition of ''Federal intergovernmental mandate'' duties that arise from participation in a voluntary federal program. The Agency's analysis of compliance with the Unfunded Mandates Reform Act (UMRA) of 1995 found that the proposed rulemaking imposes no enforceable duty on any State, local, or tribal governments or the private sector. Thus, today's proposal is not subject to the requirements of § 202 and § 205 of UMRA.

H . National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Pub L. No. 104–113, § 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This proposed rulemaking does not involve technical standards. In 1997, EPA in cooperation with NRC developed a testing guidance for sampling and testing of mixed waste. Facilities subject to this rulemaking may continue to use that guidance which allows analysis of smaller samples, thus reducing exposure of workers to radiation hazards.

I. Paperwork Reduction Act

Under the implementing regulations for the Paperwork Reduction Act, an agency is required to certify that any agency-sponsored collection of information from the public is necessary for the proper performance of its functions, has practical utility, is not unnecessarily duplicative of information otherwise reasonably accessible to the agency, and reduces to the extent practicable and appropriate the burden on those required to provide the information (5 CFR 1320.9). Any proposed collection of information must be submitted, along with this certification, to the Office of Management and Budget for approval before it goes into effect.

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1922.01) and a copy may be obtained from Sandy Farmer, OPPE Regulatory Information Division; U.S. Environmental Protection Agency (2137); 401 M St., S.W.; Washington, D.C. 20460 or by calling (202) 260–2740.

This information collection is required to provide documentation of conditional exemption from RCRA Subtitle C requirements. The exemptions from RCRA Subtitle C under today's proposed action would require no government approval before being effective. As such, information collection, maintenance and reporting issues are especially important due to the self-implementing nature of this action. Successful implementation of

today's proposal will depend upon the documentation, certification and verification provided by the information collection.

The general authority for this proposal is § 2002(a), 3001, 3002, 3004, 3006 and 3007 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6912(a), 6921, 6922, 6924, and 6926. To the extent that this rule imposes any information collection requirements under existing RCRA regulations promulgated in previous rulemakings, those requirements have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and have been assigned OMB control numbers 2050–0009 (ICR no. 1573, Part B Permit Application, Permit Modifications, and Special Permits); 2050–0120 (ICR 1571, General Facility Hazardous Waste Standards); 2050–0028 (ICR 261, Notification of Hazardous Waste Activity); 2050–0034 (ICR 262, RCRA Hazardous Waste Permit Application and Modification, Part A); 2050–0039 (ICR 801, Requirements for Generators, Transporters, and Waste Management Facilities under the Hazardous Waste Manifest System); 2050–0035 (ICR 820, Hazardous Waste Generator Standards); and 2050–0024 (ICR 976, 1997 Hazardous Waste Report).

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR parts 9 and 48 CFR chapter 15. This rule proposes new information collection requirements subject to OMB review under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* Facilities must notify EPA or the Authorized State of their claim for conditional exemption for a storage unit to be eligible for a conditional exemption for stored low-level mixed waste. If they do not choose to claim a conditional exemption, generators will have to comply with the existing Subtitle C recordkeeping and reporting requirements for the low-level mixed wastes they generate. This rule also proposes notification requirements for generators or treaters of LLMW and eligible NARM seeking a conditional exemption from the definition of hazardous waste which would allow disposal of the waste meeting the conditions for exemption in low-level radioactive waste disposal facilities licensed by NRC or NRC Agreement States. If the generator or treater of LLMW chooses not to claim an exemption, they remain subject to the existing hazardous waste disposal requirements including compliance with LDR treatment standards.

Some of the proposed requirements contained in today's action entail new reporting and recordkeeping requirements for members of the regulated public, if such change is adopted. EPA is interested in comments on any and all aspects of potential paperwork requirements, and in particular on how they should be structured to fulfill the requirements that they have practical utility, are not unnecessarily duplicative of other available information, and are the least burdensome necessary to ensure that the disposal of conditionally exempted low level mixed waste is safely managed.

If generators choose to avail themselves of the regulatory flexibility discussed in this proposal, they will be subject to notification and recordkeeping requirements described above. However, such notification and recordkeeping would replace the paperwork burden required for treatment and storage permits for their low-level mixed wastes if they did not claim a conditional exemption. States (but not Tribes) would have additional recordkeeping requirements for generators' claims for conditional exemption notices for storage units, and review of the self-implementing reinstatement notices for generators who fail to meet all the conditions for storing mixed waste and correct any violations.

We have prepared a full Information Collection Request (ICR) in support of today's action. The total annual public burden associated with this exemption is estimated to average 3.6 hours per respondent. The reporting burden is estimated to average 1.9 hours per respondent annually, and includes time for reading the regulations and preparing and submitting notifications. The recordkeeping burden is estimated to average 1.7 hours per respondent annually, and includes the time for recording the results of inventories and inspections and maintaining records pertaining to the mixed waste exemption.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Comments are requested on the need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, OPPE Regulatory Information Division; U.S. Environmental Protection Agency (2137); 401 M St., S.W.; Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., N.W., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after November 19, 1999, a comment to OMB is best assured of having its full effect if OMB receives it by December 20, 1999. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

XI. List of Comments Being Requested By EPA in This Proposal

In this proposal, we are seeking comment on several issues that concern stakeholders potentially affected by this rule, and the public. Please note, even if you commented on the Advance Notice of Proposed Rulemaking (64 FR 10063–73, March 1, 1999), EPA is seeking your comments on this proposal. Even if you submitted comments on the March 1, 1999 ANPR, you must submit comments on this revised and expanded proposal by the deadline listed above in order to have your comments considered for this proposed rulemaking. Below, we provide a list of these comment requests, cross-referenced with the applicable section of the proposal.

Storage

—We seek comment on ways we propose to address the issue of dual regulation of LLMW storage, treatment, transportation, and disposal. (III.A.)

—We would appreciate comments regarding the standard to use for determining when the decayed waste

would reenter RCRA Subtitle C management. (V.A.1.)

—We invite comment on whether a time limit may be appropriate, and, if so, on what basis that time limit might be established. (V.A.2.)

—We invite comment on how waste being stored for decay under 10 CFR 20.2001(a)(2) and 10 CFR part 35 can be completely decayed while at the same time reenter RCRA Subtitle C without a gap in time during which the waste is not regulated as either a hazardous or radioactive. Please indicate in your comment what mixed wastes you generate that have radionuclides with activity levels which would not qualify for the conditional exemption we are proposing if it were based on whichever occurred first— ten half-lives of decay or not registering above background levels. Also indicate how this limitation would affect your management of the waste. (V.A.2).

—We seek comment on whether this condition should be: broad (and include the loss of the exemption if any LLW storage requirement of the NRC or Agreement State license is not met); or more specific (and limit the loss of the exemption to those violations which may result in an environmental impact). (V.B.2.(b))

—We request comment regarding both the definition of ''on-site'' and the appropriateness of extending a conditional exemption to facilities that own/operate storage facilities that do not meet our current definition of ''on-site.''(V.B.2.(c))

—We also seek comment on whether the conditional exemption should include a storage facility which serves as a consolidation point for single entity. (V.B.2.(c))

—We request comment on whether we should include in the conditional exemption for storage those mixed waste treatment facilities that manage wastes from other generators. (V.B.2)

—We are interested in additional information regarding the safety of commercial TSDFs that could provide a basis for expanding the scope of the exemption to include off-site storage at commercial TSDFs. (V.B.2)

Disposal

—We are seeking comment and supporting information concerning the applicability of this proposal to hazardous waste contaminated with NARM. (VI.B.1)

—We are seeking comment on whether to provide for a 90-day waiting period during reclaiming of an exemption. (VI.D.4)

—We request comment on whether, for any reason, this conditional exemption should apply only to hazardous soils contaminated with radioactive waste and treated to LDR standards derived from the original waste codes, rather than to soils treated to alternative soil treatment standards. (VI.E.1)

—We are asking for public comments on the approach of a state approved site-specific, risk-based alternative to allow the disposal of hazardous waste contaminated with radioactivity in any LLRWDFs including DOE's LLRWDFs. (VI.F.)

—We seek comments on the site-specific risk-based variance approach, and the types of guidance documents needed by EPA for site-specific risk modeling. (VI. F.)

—We also seek comments on whether this approval would be preferred over the proposed conditional exemption. (VI. F.)

—We are soliciting comments on whether we need to consider, as a condition for exemption, groundwater monitoring for chemical releases. (VI. G.)

—We are requesting groundwater monitoring data from LLRWDFs. (VI. G.)

—We request comment on whether for any reason under this conditional exemption, we should require LLRWDFs to provide RCRA-like financial assurance for cleanup of RCRA hazardous constituents. (VI. G.)

XII. Supporting Documents

1. EPA—Consent Decree. HWIR Settlement Agreement, April 11, 1997.

2. EPA—Side-bar letter to EEI/USWAG dated April 7, 1997.

3. ''Review of Waste Management Practices and Compliance History at Nuclear Power Plants and Other Entities that Generate Low-Level Mixed Waste.'' April 12, 1999.

4. ''Comparison of the EPA's RCRA Requirements and the NRC's Licensing Requirements for the On-site Treatment (In Tanks and Containers) and Storage of Low-Level Mixed Wastes at Nuclear Facilities'', September 30,1999.

5. Comment Summary Document—Approach to Reinventing Regulations of Storing Mixed Low-Level Radioactive Waste; Advance Notice of Proposed Rulemaking (ANPR), September 21,1999.

6. Report to Utility Solid Waste Activities Group and Utility Nuclear Waste Management Group on Comparative Assessment of the Environmental Protection Agency's Regulations for Hazardous Waste Tank Systems (40 CFR part 265, Subpart J) and Comparable Nuclear Regulatory Commission Requirements, July 1988.

7. Technical Evaluation on Document for the Disposal of Mixed Waste at Low-Level Radioactive Waste Disposal Facilities, Draft Technical Background Document, July1999.

8. National Profile on Commercially Generated Low-Level Radioactive Mixed Waste, NUREG/CR–5938, December 1992.

9. Meeting Notes for EPA Meeting with Low-Level Radioactive Waste Disposal Facilities, December 7, 1998.

10. RCRA Hazardous Constituents and Waste Codes Associated with Mixed Waste, December 1997.

11. Joint State/EPA Workshop on Mixed Waste Rulemaking, October 7–9, 1998, Meeting Summary.

12. Comparison of NRC and EPA's Waste Tracking and Related Record Keeping Requirements, July 1999.

13. Technical Alternatives Considered for Evaluating Protectiveness of Low-Level Waste Disposal Facilities, July 21, 1999.

14. Regulatory Impact Analysis: Relief from Regulatory Requirements for Storage and Disposal of Mixed Waste, July 1999.

15. Summary of Public Comments on ''Contingent Management of Mixed Waste'' Submitted in Response to the 1995 HWIR Proposal, July 1999.

16. The Management of Mixed Low-Level Radioactive Waste in the Nuclear Power Industry, NUMARC/NESP–006, Nuclear Management Resources Council, Inc., Washington, D.C., January 1990.

17. Regulatory Impact Analysis: Relief from Regulatory Requirements for Storage and Disposal of Mixed Waste, Background Documents, August 1999.

List of Subjects in 40 CFR Part 266

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements, Waste treatment and disposal.

Dated: October 29, 1999.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble 40 CFR part 266 is proposed to be amended as follows:

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

1. The authority citation for part 266 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921,6922, 6924, 6926, 6927, and 6934.

2. Part 266 is amended by adding subpart N to read as follows:

Subpart N—Conditional Exemption for Low-Level Mixed Waste Storage, Treatment, Transportation and Disposal

Terms

Sec.

266.210 What special definitions apply to this subpart?

Storage Conditional Exemption and Eligibility

266.220 What does a conditional exemption for stored mixed waste do?

266.225 What stored mixed wastes are eligible?
266.230 What must you do to qualify for a storage exemption?

Treatment

266.235 What waste treatment does this exemption allow?

Loss of Conditional Exemption

266.240 How could you lose your conditional exemption?
266.245 If you lose the exemption, can it be reclaimed?

Record Keeping and Reentry Into RCRA

266.250 What records must you keep besides those required by your NRC or Agreement State license?
266.255 When is your low-level mixed waste no longer eligible for the Storage Conditional Exemption?

Transportation and Disposal Conditional Exemption

266.305 What does the Transportation and Disposal Conditional Exemption do?
266.310 Is your waste eligible for the Transportation and Disposal Conditional Exemption?
266.315 What are the conditions you must meet?

Treatment Standard for Disposal

266.320 What treatment standard must your waste, either as-generated or treated, meet?

Notification, Transportation, and Manifest

266.325 Before shipping exempt waste, whom must you notify?
266.330 How must you notify them?
266.335 Must you wait for any approvals?
266.340 What if the information in your notification changes?
266.345 What are the transportation and manifest conditions you must meet?
266.350 When does the exemption take effect?

Disposal Facility

266.355 Where must you dispose of exempt waste to keep this exemption?
266.360 Must your waste be containerized before disposal at the LLRWDF to keep this exemption?

Record Keeping

266.365 What records must you keep at your facility and for how long?
266.370 When must you make records available?

Loss of Conditional Exemption

266.375 How will your RCRA program agency verify your Transportation and Disposal Conditional Exemption?
266.380 How could you lose your Transportation and Disposal Conditional Exemption?
266.385 If you lose the Transportation and Disposal Conditional Exemption can it be reclaimed?

Subpart N—Conditional Exemption for Low-Level Mixed Waste Storage and Disposal

Terms

§ 266.210 What special definitions apply to this subpart?

This subpart uses the following special definitions:

Agreement State means a state that has entered into an agreement with the NRC under subsection 274b of the Atomic Energy Act of 1954, as amended (68 Stat. 919), to assume responsibility for regulating within its borders source, special nuclear, or byproduct material in quantities not sufficient to form a critical mass.

Eligible NARM means NARM that meets the acceptance criteria of a LLRWDF licensed by NRC or an Agreement State in accordance with 10 CFR part 61 and is contaminated by hazardous waste, and therefore, is eligible for the transportation and disposal conditional exemption.

Facility as defined in 40 CFR 260.10.

Hazardous waste means any material which is defined to be hazardous waste in accordance with 40 CFR 261.3, ''Definition of Hazardous Waste.''

Land Disposal Restriction (LDR) treatment standards means treatment standards, under 40 CFR part 268, that a RCRA hazardous waste must meet before it can be disposed on land in a RCRA hazardous waste disposal landfill.

License means a license issued by the Nuclear Regulatory Commission, or NRC Agreement State, to users that manage radionuclides regulated by NRC, or NRC Agreement States, under authority of the Atomic Energy Act of 1954, as amended.

Low-Level Mixed Waste (LLMW) is a low-Level radioactive waste containing a RCRA hazardous waste component.

Low-Level radioactive waste (LLW) is a radioactive waste containing source, special nuclear, or by-product material which is not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, byproduct material as defined in section 11(e)(2) of the Atomic Energy Act or NARM. (See also NRC definition of ''waste'' at 10 CFR 61.2)

Low-Level Radioactive Waste Disposal Facility (LLRWDF) means a disposal facility licensed by the NRC or an Agreement State for the disposal of low-Level waste.

Mixed Waste means a waste that contains both RCRA hazardous waste and source, special nuclear, or by-product material subject to the Atomic Energy Act of 1954, as amended.

Mixed Waste Treatment Facility means a waste treatment facility permitted by EPA or an Authorized State to treat hazardous waste and licensed by the NRC or an Agreement State to manage radioactive waste.

Naturally Occurring and/or Accelerator-produced Radioactive Material (NARM) means radioactive materials not covered under the AEA that are naturally occurring or produced by an accelerator. The naturally occurring radioactive material (NORM) is defined below. NARM is regulated by the States under State law, or by DOE under DOE Orders.

Naturally Occurring Radioactive Material (NORM), a subset of NARM, refers to materials not covered under the AEA whose radioactivity has been enhanced usually by mineral extraction or processing activities.

NRC means the Nuclear Regulatory Commission. or its duly authorized representative (for example, an NRC Agreement State that regulates management of low-Level waste).

RCRA program agency means EPA, or the state agency authorized to implement the RCRA program.

We, within this subpart, means the EPA, or the EPA Regional Office.

You means a generator, treater, or other handler of low-level mixed waste except for the storage exemption provisions in § 266.220–266.255 where it means only a generator.

Storage Conditional Exemption and Eligibility

§ 266.220 What does a conditional exemption for stored mixed waste do?

A conditional exemption exempts certain low-Level mixed waste from the regulatory definition of hazardous waste in § 261.3 during storage if you, as the generator, have a storage unit and waste which meet specified conditions in §§ 266.225 through 266.255.

§ 266.225 What stored mixed wastes are eligible?

Low-Level mixed waste defined in § 266.210 is eligible for a conditional exemption if managed subject to NRC or Agreement State regulations, and if it is:

(a) Generated at your facility (Mixed waste generated at another facility and shipped to your facility for storage or treatment requires a storage permit and is ineligible for the storage exemption.);

(b) Stored on-site in a tank or container meeting the requirements of your NRC or Agreement State license for storing low-Level waste; and

(c) Stored in compliance with chemical compatibility requirements of a tank or container (See § 264.177, or

§ 264.199 of this chapter), or (§ 265.177, or § 265.199 of this chapter).

§ 266.230 What must you do to qualify for a storage exemption?

You must meet all the following conditions.

(a) Have a valid NRC or Agreement State license.

(b) Comply with the requirements of your license for storing low-Level mixed waste.

(c) Meet the eligibility requirements of § 266.225.

(d) Notify us (EPA) by certified mail, return receipt requested, that you claim a conditional exemption for a storage unit containing low-Level mixed waste. You must notify us of your claim either within 90 days of the effective date of this rule in your State, or within 90 days of when a storage unit is first used to store LLMW for which you claim a conditional exemption.

(e) Certify that facility personnel who manage stored mixed waste have been trained in a manner that ensures that the low-Level mixed waste is safely managed and includes training in chemical waste management and hazardous materials incidence response as outlined in the personnel training standards found in 40 CFR 265.16(a)(3).

(f) Inventory your stored low-level mixed waste at least annually; inspect it at least quarterly for compliance with the other conditions of the paragraph; update your inventory records of conditionally exempt LLMW quarterly; and maintain records for three years after the waste is sent for disposal, or in accordance with NRC requirements, whichever is longer.

(g) Maintain an accurate emergency plan and provide it to all local authorities who may have to respond to an emergency. Your plan must describe emergency response arrangements with local authorities; describe evacuation plans; list the names, addresses, and telephone numbers of all facility personnel qualified to work with local authorities as emergency coordinators; and list emergency equipment. (See 40 CFR part 265, subpart D.)

Treatment

§ 266.235 What waste treatment does this exemption allow?

Allowable treatment of your low-Level mixed waste includes only on-site treatment within a tank or container covered by the provisions of your NRC or Agreement State license. The treatment may include solidification, neutralization, or other forms of stabilization, but excludes thermal treatment, such as incineration.

Loss of Conditional Exemption

§ 266.240 How could you lose your conditional exemption?

(a) The conditional exemption applies only while all the conditions are met. (See § 266.230)

(b) You automatically lose your exemption for failure to meet any of the conditions. (See § 266.230).

(c) You must report to us and the NRC or Agreement State in writing of any failure to meet a condition within 30 days of learning of the failure. If the failure may endanger human health or the environment, you must also notify us, EPA or RCRA program agency orally within 24 hours. Failures that endanger human health or the environment include, but are not limited to, discharge of a CERCLA reportable quantity or other leaking or exploding tanks or containers, or detection of radionuclides or hazardous constituents in the leachate collection system of a storage area. If the failure may endanger human health or the environment, you must follow the provisions of your emergency contingency plan.

§ 266.245 If you lose the exemption, can it be reclaimed?

(a) You may reclaim your exemption if:

(1) You again meet the requirements of § 266.230; and

(2) You send us, the RCRA program agency, a notice that you are reclaiming the exemption. The notice must do the following:

(i) Explain the circumstances of each failure.

(ii) Certify that you have corrected each failure that caused you to lose the exemption and that your waste again meets all the conditions as of the date you specify.

(iii) Demonstrate that each failure is not likely to recur because of specific steps (list them) that you have implemented in your LLMW compliance activities.

(iv) Include any other information you want us to consider when we review your notice reclaiming the exemption.

(b) We may terminate a reclaimed conditional exemption if we find that your claim is inappropriate based on factors such as: you have failed to correct the problem; you explained the circumstances of the violation unsatisfactorily; or you failed to show that the violation is unlikely to recur. In reviewing a reclaimed conditional exemption under this section, we may add requirements to the exemption to ensure and document proper storage to protect human health or the environment.

Record Keeping and Reentry Into RCRA

§ 266.250 What records must you keep besides those required by your NRC or Agreement State license?

You must keep your initial notification records and records of your LLMW inventories and inspections. At a minimum you must inventory waste annually, inspect quarterly, and update your records of conditionally exempt LLMW at least quarterly. You must maintain storage records for three years after the waste is sent for disposal, or in accordance with NRC requirements under 10 CFR part 20, whichever is longer.

§ 266.255 When is your low-Level mixed waste no longer eligible for the Storage Conditional Exemption?

(a) When your LLMW has met the requirements of your NRC or Agreement State license for decay-in-storage and can be disposed of as non-radioactive waste, then the conditional exemption for storage no longer applies. At that point your waste is subject to hazardous waste regulation as ''newly generated'' hazardous waste under the relevant sections of 40 CFR Parts 260–271.

(b) When your waste is transported off-site for any reason other than to a LLRWDF under the Disposal Conditional Exemption at § 266.305, it is no longer eligible for the Storage Conditional Exemption.

Transportation and Disposal Conditional Exemption

§ 266.305 What does the Transportation and Disposal Conditional Exemption do?

The conditional exemption for transportation and disposal gives you—the mixed waste generator, treater, or other handler—an alternate way to manage your low-Level mixed waste. If this waste meets Land Disposal Restrictions treatment standards, and is subject to NRC or Agreement State's transportation, manifest and disposal regulations, it will be exempted from RCRA Subtitle C hazardous waste manifest, transportation and disposal regulations. Currently, low-Level mixed waste meeting LDR treatment standards must be managed in accordance with both NRC or Agreement State's and RCRA Subtitle C's transportation, manifest and disposal regulations. To obtain and keep the Transportation and Disposal Conditional Exemption, you must meet all conditions under the Transportation and Disposal Conditional Exemption at all times.

§ 266.310 Is your waste eligible for the Transportation and Disposal Conditional Exemption?

To be eligible for this exemption, your waste must be:

(a) A low-Level radioactive waste, or NARM waste as defined in § 266.210 which meets the acceptance criteria of a LLRWDF licensed by the NRC or an Agreement State in accordance with 10 CFR part 61; and

(b) A RCRA hazardous waste as defined in 40 CFR 261.3.

§ 266.315 What are the conditions you must meet?

You must do the following to obtain and keep the Transportation and Disposal Conditional Exemption:

(a) Meet and continue to meet LDR treatment standards per § 266.320.

(b) Have received written confirmation that you have notified the designated regulatory agencies of the exemption per § 266.325(a), § 266.330(a), and § 266.340.

(c) Even if you self-regulate under the Atomic Energy Act, you must manifest and transport the waste according to NRC regulations per § 266.345.

(d) Ensure the exempted waste is containerized per § 266.360, and disposed at a designated LLRWDF per § 266.355.

(e) Keep and submit records of the exemption as required under § 266.365, and § 266.370.

Treatment Standard For Disposal

§ 266.320 What treatment standard must your waste, either as-generated or treated, meet?

Your LLMW or eligible NARM must meet, or be treated to meet, LDR treatment standards specified in §§ 268.40–268.49 of this chapter. The waste must also meet RCRA definition of non-wastewater as specified in 40 CFR 268.2(d) of this chapter prior to disposal.

Notification, Transportation and Manifest

§ 266.325 Before shipping exempt waste, whom must you notify?

(a) You must notify the following parties, in writing, every time you intend to claim an exemption for a newly generated waste stream (a waste stream whose RCRA hazardous waste codes differ from those of the previously claimed waste streams):

(1) The RCRA program agency (EPA or state) regulating your low-level mixed waste activities;

(2) The RCRA program agency (EPA or state) in the state where the LLRWDF is located; and

(3) The NRC or Agreement State regulating the LLRWDF where the waste will be disposed.

(b) You must also notify the LLRWDF receiving your waste, in writing, every time you plan to ship any exempted waste to the LLRWDF.

§ 266.330 How must you notify them?

(a) You must notify all parties in § 266.325(a) by sending your notification by certified mail with return receipt requested. A ''return receipt'' is any document that demonstrates the receipt of the notification package by the regulatory agencies. It can be the receipt of delivery by the U.S. Postal Service, or a mail delivering service. Include at least the following in the notice:

(1) A dated cover letter signed by an officer or authorized employee that claims the exemption and includes the following:

(i) Your facility's name, address, and RCRA ID number.

(ii) The RCRA hazardous waste codes.

(2) A brief, general description of the process or operation that generated the waste.

(3) The quantity of each waste stream you will ship for disposal and an estimate of the average monthly, maximum monthly, average annual, and maximum annual quantities of the waste for which you are claiming an exemption.

(4) Name, address, and NRC or Agreement State license number of the LLRWDF that has agreed to receive your waste.

(5) A certification for compliance with LDR treatment standards as follows:

(i) A generator at § 268.7(a)(3)(i) of this chapter.

(ii) Treatment facilities at § 268.7(b)(4) of this chapter.

(6) A certification signed by you, or your authorized representative, that the information contained in the notification package is true, accurate, and complete.

(b) You must notify the LLRWDF by certified mail with return receipt requested. Include at least the following:

(1) The cover letter described in § 266.330(a)(1).

(2) The shipment number that will appear on block number 5 of NRC or Agreement State's Uniform Low-Level Radioactive Waste Manifest Form 540.

§ 266.335 Must you wait for any approvals?

Your exemption is self-implementing. The parties you notify needn't review your notification or approve the exemption. You may ship waste that meets LDR treatment standards to the LLRWDF once certified mail receipts have come back to you from all parties required to be notified.

§ 266.340 What if the information in your notification changes?

(a) Submit any change in any information submitted under § 266.330 to all parties you notified initially.

(b) Do it within 10 business days of first learning of a change.

§ 266.345 What are the transportation and manifest conditions you must meet?

Even if you self-regulate under the authority of the Atomic Energy Act, you must meet the NRC or Agreement State transportation requirements in 10 CFR 71.5, and the NRC or Agreement State manifest requirements in 10 CFR 20.2006. Your exempted waste is not subject to the RCRA hazardous-waste transportation and manifest requirements.

§ 266.350 When does the exemption take effect?

Your waste becomes exempt from RCRA Subtitle C manifest, transportation and disposal once you do the following:

(a) Your waste meets LDR treatment standards;

(b) You have received return receipts that you have notified the specified regulatory agencies;

(c) You have manifested the waste according to NRC or Agreement State manifest regulation at 10 CFR 20.2006; and

(d) You have placed the waste on a transportation vehicle bound for an LLRWDF licensed by NRC or an Agreement State.

Disposal Conditions

§ 266.355 Where must you dispose of exempted waste to keep this exemption?

You must dispose of your RCRA-exempted waste in a LLRWDF licensed by NRC or Agreement State under 10 CFR part 61.

§ 266.360 Must your waste be containerized before disposal at the LLRWDF to keep this exemption?

You must arrange to have your exempted waste containerized before it is placed in a disposal cell. The container can not be cardboard or fiberboard boxes.

Record Keeping

§ 266.365 What records must you keep at your facility and for how long?

You must keep records as follows:

(a) You must continue to follow existing applicable record keeping requirements under §§ 264.73 and 268.7 of this chapter in order to demonstrate

that your waste has met LDR treatment standards prior to your claiming the exemption.

(b) You must keep a copy of all notifications required under § 266.330, sent to parties listed in § 266.325 of this subpart for as long as the Mixed Waste exemption continues to be active, and for the three years that follow.

(c) You must keep a copy of return receipts of the notification package from all those parties for as long as the Mixed Waste exemption continues to be active, and for the three years that follow.

(d) You must keep a copy of all of NRC or Agreement State's radioactive waste manifests which included a shipment of the exempted waste, and you must attach the accompanying cover letter as described in § 266.330(a)(1) to it. Keep these records until closure of the disposal facility, or closure of your facility if it happens before the disposal facility closure.

(e) You must keep a copy of any notice to any regulatory agency that tells of any change to your initial notification for as long as the Mixed Waste exemption continues to be active, and for the three years that follow.

(f) For generators who self-regulate under the Atomic Energy Act, in addition to the records specified in § 266.365(a) through (e), you must keep all other documents related to tracking the waste as required under 10 CFR 20.2006.

§ 266.370 When must you make records available?

Make all records relative to your exemption available to your RCRA program agency in these cases:

(a) Immediately during an on-site inspection.

(b) Within five business days when and as requested by EPA.

Loss of Conditional Exemption

§ 266.375 How will your RCRA program agency verify your Transportation and Disposal Conditional Exemption?

Your RCRA program agency may inspect your facility, audit your records regarding the exemption, obtain samples and perform any other activities authorized under RCRA including under section 3007, 42 U.S.C. 6927 or other information gathering authority. In an enforcement action, the burden of proof to establish compliance with this subpart falls on you. Nothing in Subpart N shall be interpreted or applied to restrict any inspection or enforcement authority under RCRA, 42 U.S.C. 6901 *et seq*. Notwithstanding any other provisions of these regulations, actions may also be brought pursuant to Section 7003 of RCRA, 42 U.S.C. 6973, relating to imminent and substantial endangerment.

§ 266.380 How could you lose your Transportation and Disposal Conditional Exemption?

(a) If you fail to satisfy any conditions listed under § 266.315 you will lose your manifest, transportation, and disposal exemption. When you lose your exemption, you must immediately manage your waste as RCRA hazardous waste and you may be subject to enforcement action and fines and penalty under RCRA.

(b) If you fail to satisfy the requirements listed under § 266.325(b) and/or § 266.330(b), you may be subject to enforcement action and fines and penalty under RCRA. However, you will not lose your manifest, transportation, and disposal exemptions.

(c) If you fail to satisfy any of the conditions and requirements under the Transportation and Disposal Conditional Exemption you must notify all parties listed in § 266.325(a) in writing, with return receipt requested, of the violation within 30 days of learning of the violation.

§ 266.385 If you lose the Transportation and Disposal Conditional Exemption can it be reclaimed?

(a) You may reclaim your exemption if:

(1) You again meet the requirements of § 266.315; and

(2) You send us, the RCRA program agency, a notice that you are reclaiming the exemption. The notice must do the following:

(i) Explain the circumstances of each failure.

(ii) Certify that you have corrected each failure that caused you to lose the exemption and that your waste again meets all the conditions as of the date you specify.

(iii) Demonstrate that each failure is not likely to recur because of specific steps (list them) that you have implemented in your LLMW compliance activities.

(iv) Include any other information you want us to consider when we review your notice reclaiming the exemption.

(b) We may terminate a reclaimed conditional exemption if we find that your claim is inappropriate based on factors such as: you have failed to correct the problem; you explained the circumstances of the violation unsatisfactorily; or you failed to show that the violation is unlikely to recur. In reviewing a reclaimed conditional exemption under this section, we may add requirements to the exemption to ensure and document proper waste management to protect human health or the environment.

[FR Doc. 99–29068 Filed 11–18–99; 8:45 am]

BILLING CODE 6560–50–p

Federal Register

Friday
November 19, 1999

Part IV

Department of Health and Human Services

Office of Inspector General

42 CFR Part 1001

Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991–AA91

Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements

AGENCY: Office of Inspector General (OIG), HHS

ACTION: Interim final rule with request for comment.

SUMMARY: In accordance with section 216 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, this interim final rule establishes two new safe harbors from the anti-kickback law (section 1128B(b) of the Social Security Act) to provide protection for certain managed care arrangements. The first safe harbor protects certain financial arrangements between managed care plans and individuals or entities with whom they contract for the provision of health care items and services, where Federal health care programs pay such plans on a capitated basis. The second safe harbor protects certain financial arrangements between managed care plans (including employer-sponsored group health plans) and individuals or entities with whom they contract for health care items and services with respect to services reimbursed on a fee-for-service basis by a Federal health care program provided that such individuals and entities are placed at substantial financial risk for the cost or utilization of items or services furnished to Federal health care program beneficiaries. Each of these safe harbors set forth standards that will result in the particular arrangement being protected from criminal prosecution and civil or administrative sanctions under the anti-kickback provisions.

DATES: *Effective date:* This rule is effective on November 19, 1999. *Comment period:* To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on January 18, 2000.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–54–IFC, Room 5246, Cohen Building 330 Independence Avenue, S.W., Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: Julie E. Kass, Senior Counsel, Office of Counsel to the Inspector General, (202) 205–9501; or Joel Schaer, Regulations Officer, Office of Counsel to the Inspector General, (202) 619–1306.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Anti-Kickback Statute

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a–7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a Federal health care program (including Medicare and Medicaid). The offense is a felony punishable by fines of up to $25,000 and imprisonment for up to 5 years. Section 2 of the Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA) authorizes the exclusion of an individual or entity from participation in the Medicare and State health care programs if it is determined that the party has violated the anti-kickback statute. In addition, the Balanced Budget Act of 1997, Public Law 105–33, amended section 1128A(a) of the Act to include an administrative civil money penalty provision for violating the anti-kickback statute. The administrative sanction is $50,000 for each act and an assessment of not more than 3 times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose. (See section 1128A(a)(7) of the Act; 42 U.S.C. 1320a–7a(a)(7)).

The anti-kickback statute contains five statutory exceptions from the statutory prohibitions. The exceptions are for certain discounts obtained by a provider and disclosed to the Federal health care program, compensation paid to a bona fide employee by an employer, amounts paid to a group purchasing organization by a vendor subject to certain conditions, waivers of coinsurance by Federally qualified health centers, and remuneration paid as part of a risk-sharing arrangement. The last exception is the subject of this rulemaking.

Section 14 of MMPPPA also required the OIG to promulgate regulations specifying those payment and business practices that, although potentially capable of inducing referrals of business under the Medicare and State health care programs, would not be subject to criminal prosecution under section 1128B of the Act and that will not provide a basis for administrative sanctions under sections 1128(b)(7) or 1128A(a)(7) of the Act. (See section 2 of Pub. L. 100–93.) Congress intended that the regulations setting forth various ''safe harbors'' would be periodically updated to reflect changing business practices and technologies in the health care industry.

The failure of an arrangement to fit inside a safe harbor or statutory exception does *not* mean that the arrangement is illegal. It is incorrect to assume that arrangements outside of a safe harbor are suspect due to that fact alone. That an arrangement does not meet a safe harbor only means that the arrangement does not have guaranteed protection and must be evaluated on a case-by-case basis.

The anti-kickback statute potentially applies to many managed care arrangements because a common strategy of these arrangements is to offer physicians, hospitals and other providers increased patient volume in return for substantial fee discounts. Because discounts to managed care plans can constitute ''remuneration'' within the meaning of the anti-kickback statute, a number of health care providers and managed care plans have expressed concern that many relatively innocuous, or even beneficial, commercial managed care arrangements implicate the statute and may subject them to criminal prosecution and administrative sanctions. In response to these concerns, we issued final safe harbor regulations for managed care arrangements on January 25, 1996 (61 FR 2122) to protect certain managed care arrangements that we did not believe posed any significant risk of fraud or abuse. (See 42 CFR 1001.952(m)). We are soliciting comments on whether the current managed care safe harbor should be removed in light of this rulemaking so as to avoid confusion.

We recognize that many managed care arrangements exist in the marketplace today that do not fall within a safe harbor, but are not illegal under the anti-kickback statute. Such arrangements must be analyzed on a case-by-case basis. Any individual or entity with questions regarding whether a specific arrangement violates the anti-kickback statute may submit an advisory opinion request to the OIG in accordance with regulations set forth in 42 CFR part 1008.

B. Section 216 of HIPAA

1. Summary of Statutory Provision

In section 216 of HIPAA, Congress created a new statutory exception to the anti-kickback statute that covers remuneration in accordance with two categories of risk-sharing arrangements. The first category is ''any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1876 (of the Social Security Act) * * *'' The second category is ''any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity * * * if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide.'' Congress directed the Department to develop regulations implementing the exceptions using a negotiated rulemaking process.

2. Negotiated Rulemaking Process

The negotiated rulemaking process began in the spring of 1997, and on March 7, 1997, a facilitator with the Department's Departmental Appeals Board issued a convening report to the Inspector General, setting out findings and recommendations on the use of a negotiated rulemaking process for these regulations and identifying industry and consumer representatives who, based on their interests, should serve on the committee. On May 23, 1997, the OIG issued a notice of intent to form a Negotiated Rulemaking Committee, in accordance with the Negotiated Rulemaking Act of 1990, Public Law 101–648, as amended by Public Law 102–354 (5 U.S.C. 561 *et seq.*), and requested public comments on whether those interests affected by the key issues of the negotiated rulemaking had been identified (62 FR 28410). After review of the comments, the Secretary appointed a committee consisting of 23 parties representing all of the major groups identified as having a significant interest in these regulations. The negotiated rulemaking committee was comprised of the following groups:

- American Association of Health Plans
- American Association of Retired Persons
- American Hospital Association
- American Health Care Association
- American Medical Association
- American Medical Group Association
- Blue Cross Blue Shield Association
- Consumer Coalition for Quality Health Care
- Coordinated Care Coalition
- Department of Justice
- Federation of American Health Systems
- Health Insurance Association of America
- Health Insurance Manufacturers Association
- Independent Insurance Agents of America/National Association of Health
- Underwriters/National Association of Life Underwriters
- National Association of Chain Drug Stores
- National Association of Community Health Centers
- National Association of Insurance Commissioners
- National Association of Medicaid Fraud Control Units
- National Association of State Medicaid Directors
- National Rural Health Association
- Office of Inspector General, DHHS
- Pharmaceutical Research and Manufacturers of America
- The IPA Association of America

The committee was charged with reaching consensus on the basic content of interim final regulations relating to section 216 of HIPAA. Committee consensus was defined as a unanimous concurrence of all committee members, provided that there was a quorum of two-thirds of the committee members present. Unanimous concurrence with respect to a committee decision meant only that the committee members ''could live with'' the particular decision.

The committee held seven multi-day negotiating sessions beginning in June 1997. During the sessions, the committee made significant progress in developing new regulations. On January 22, 1998, the committee unanimously concurred on the committee statement that formed the basis of this rulemaking when considered as a whole. A copy of the committee statement can be found on the OIG web site at http://www.dhhs.gov/progorg/oig.

C. Basis for Interim Final Rulemaking

These interim final regulations will be effective upon publication. For a number of reasons, we find that good cause exists for an immediate effective date for these regulations. First, Congress specifically mandated that the regulations implementing section 216 of HIPAA should be published as interim final regulations. Second, those portions of the rule that are technically outside of the scope of section 216 of HIPAA were discussed in a public forum during the negotiated rulemaking sessions and are integral to the protections afforded under the portions of the regulation implementing section 216 of HIPAA. In addition, safe harbors do not create any affirmative obligation on any individuals or entities. They only exempt certain conduct from potential criminal and administrative sanctions. As a result, we find that the benefit conferred on the public by this rule's immediate promulgation provides good cause for it to be effective upon publication.

II. Provisions of the Interim Final Rule

In this section, we discuss the purpose and scope of the safe harbors, summarize the provisions of this interim final rule, and describe general issues that arose during the negotiated rulemaking. We then describe the individual provisions of the rulemaking and related issues discussed by the committee.

A. Purpose

The rule is intended to implement section 216 of HIPAA by creating two new regulatory safe harbors that correspond to the two categories of managed care arrangements identified in that statutory provision. The first safe harbor, set forth in § 1001.952(t), protects various financial arrangements between managed care entities that receive a fixed or capitated amount from the Federal health care programs and individuals and entities with whom the managed care entity contracts for the provision of health care items or services.

The second safe harbor, set forth in § 1001.952(u), protects contractual relationships between managed care entities and their contractors and subcontractors where the contractors and subcontractors are at *substantial financial risk* for the cost or utilization of items or services they provide or order for Federal health care program beneficiaries. As explained in detail below, the negotiated rulemaking committee recognized that there are few existing managed care arrangements that would qualify under newly-established § 1001.952(u) that are not otherwise covered by the safe harbor in newly-established § 1001.952(t). In practice, most managed care arrangements, such as employer-sponsored health plans, do *not* place their contractors and subcontractors at substantial financial risk for the cost or utilization of items or services provided to Federal health

care program beneficiaries. Typically, the contractors and subcontractors to such health plans are reimbursed directly by the Federal payor on a fee-for-service basis. Notwithstanding the fee-for-service payment arrangements, § 1001.952(u) identifies a category of arrangements that *could* qualify for protection.

B. Scope of the Safe Harbors

The safe harbors established in §§ 1001.952(t) and (u) protect remuneration between parties where the remuneration is a price reduction for the provision of health care items or services. Other remuneration, such as profit distributions from investment interests in an entity with a risk sharing arrangement, is not protected by these safe harbors. Individuals or entities seeking safe harbor protection for such arrangements may meet the requirements of another safe harbor, such as the safe harbor for investment interests in small entities set forth in § 1001.952(a)(2).

In addition, if an arrangement covers both remuneration that qualifies for protection under either § 1001.952(t) or (u), and remuneration that is not qualified for protection, the former remuneration remains protected. For example, a managed care plan may ''carve out'' transplant services from its capitated payment methodology and pay for those services on a fee-for-service basis. The remuneration for the transplant services would not be protected under these safe harbors. However, protection for the items or services covered by the capitation, assuming all safe harbor conditions are otherwise met, would not be lost. Further, an arrangement that potentially falls within more than one safe harbor need only meet the requirements of one safe harbor. The remuneration for the transplant services may be protected under a separate safe harbor, such as the personal services safe harbor (§ 1001.952(d)).

Finally, compliance with a safe harbor only provides protection from the Federal anti-kickback criminal statute and related administrative sanction authorities. Safe harbors do not apply to other laws, such as State licensure laws, antitrust laws or other Federal and State health care fraud laws. Further, the terms and definitions in these safe harbors do not apply to other laws, including but not limited to the anti-trust laws.

C. General Issues Discussed By The Committee

The literal language of section 216 of HIPAA presented several threshold problems. First, the two categories of managed care arrangements identified by section 216 of HIPAA were narrow and did not provide protection for other managed care arrangements that the committee believed presented similar low risks of fraud or abuse. For example, section 216 was passed prior to the enactment of the Balanced Budget Act of 1997, which provides both for the phasing out of section 1876 managed care contracts, and the creation of Medicare+Choice programs under the new Medicare Part C. Many of the new Medicare+Choice organizations are similar to section 1876 organizations and deserve the same extensive protection. Nevertheless, while Congress in the Balanced Budget Act changed many of the references to section 1876 in the Act to the new Medicare Part C, it did not change the reference in section 216 of HIPAA.

A similar issue arose with respect to the second category of arrangements protected by section 216. The statutory language was limited to arrangements in which the provider or supplier is at substantial financial risk for items or services that it is obligated to provide. However, as a practical matter, many effective managed care systems place the physicians at substantial risk, not for the physician services they provide directly, but for the ancillary and hospital services they order. Furthermore, the financial incentives in most managed care plans are based not on the individual performance of a physician, but on the aggregate performance of a group of physicians.

Given the shortcomings of the statutory language, the Department determined that it would exercise its authority under section 14 of the MMPPPA to expand these safe harbors beyond the legal confines of section 216. Again, section 14 of MMPPPA allows the Secretary to promulgate regulations to protect arrangements that the Department determines may technically violate the anti-kickback statute, but which pose a low risk of program fraud or abuse. Exercise of this authority permits protection of certain types of managed care arrangements that are not encompassed within the statutory language of section 216 of HIPAA. The committee statement includes these expanded provisions and specifically identifies them as areas outside of the scope of section 216.

A final conceptual issue was the definition of ''substantial financial risk.'' Some committee members wanted the rule to set forth clear ''bright line'' standards, so that both law enforcement officers and the industry would know whether a particular arrangement was protected or not. While bright line tests can potentially ''chill'' the development of some innovative managed care arrangements, any ambiguity in the scope of protection could be exploited by unscrupulous individuals or entities to engage in abusive or fraudulent activities, especially in light of the high burden of proof on the Government in criminal proceedings. Plans have the option of submitting advisory opinion requests for arrangements that do not fit within these safe harbors. Furthermore, the Department annually solicits suggestions for additions to the anti-kickback safe harbors (62 FR 65049; December 10, 1997). Moreover, we have agreed to review the target payment percentages of the numeric substantial financial risk test as more research and data become available.

D. Section 1001.952(t)—Price Reductions Offered to Eligible Managed Care Organizations

1. Overview

This safe harbor corresponds to the first category of arrangements identified in section 216 of HIPAA, which exempts certain arrangements involving ''eligible organizations under section 1876'' of the Act. Section 1876 of the Act provides for the Health Care Financing Administration (HCFA) to enter into managed care contracts with Federally-qualified health maintenance organizations (HMOs) and certain competitive medical plans that have characteristics similar to Federally-qualified HMOs. As used in section 1876 of the Act and the implementing regulations, an ''eligible organization'' encompasses both (i) Federally-qualified HMOs and competitive medical plans that have entered into either risk or cost-based managed care contracts with HCFA, and (ii) Federally-qualified HMOs that have not entered into risk or cost-based managed care contracts with HCFA.

This safe harbor recognized that eligible organizations with risk contracts under section 1876 of the Act presented little or no risk of overutilization or increased costs to the Federal health care programs, given applicable payment arrangements and regulatory oversight. When plans are paid a capitated amount for all of the services they provide regardless of the dates, frequency or type of services, there is no incentive to overutilize. In any event, even if overutilization occurs, the Federal health care programs are not at risk for these increased costs.

The safe harbor set forth in § 1001.952(t) extends protection from the anti-kickback statute beyond the

managed care arrangements under section 1876 of the Act that are specifically protected by section 216 of HIPAA. The expansion includes other programs where the Federal health care programs pay on a capitated or fixed aggregate basis, such as certain Medicare Part C plans. Further, it extends safe harbor protection ''downstream'' to cover subcontracts with other providers and entities to provide items and services in accordance with a protected managed care arrangement. So long as the Federal health care programs' aggregate financial exposure is fixed in accordance with its contract with the managed care organization, these subcontracting arrangements are protected regardless of the payment methodology, subject to the limitations set forth below.

2. Limitations

While § 1001.952(t) broadens the statutory exception in important respects, there are some important limitations. First, the broad protection for arrangements with subcontractors is limited to risk-based managed care plans that do not claim any payment from a Federal health care program other than the capitated amount set forth in the managed care plan's agreement with the Federal health care program. Where the managed care plan, its contractors or its subcontractors are permitted to seek additional payments from any of the Federal health care programs, the regulatory safe harbor protection is significantly more limited. For example, protection is not extended to arrangements with subcontractors when the contract under section 1876 of the Act is cost-based or where the prime contract is protected solely because the contracting entity is a Federally-qualified HMO. In the first instance, reimbursement from the Federal health care program is based on costs, and in the latter case, services for Medicare enrollees are reimbursed on a fee-for-service basis. In both instances, reimbursement will increase with utilization, thus providing the same incentive to overutilize as any fee-for-service payment methodology.

A second limitation on the regulatory safe harbor protection is that it only applies to remuneration for health care items and services and those items or services reasonably related to the provision of health care items and services. Section 1001.952(t) does not cover marketing services or any services provided prior to a beneficiary's enrollment in a health plan. This limitation also applies to the other new safe harbor in § 1001.952(u).

Another significant limitation is that there is no protection if the financial arrangements under the managed care agreement are implicitly or explicitly part of a broader agreement to steer fee-for-service Federal health care program business to the entity giving the discount to induce the referral of managed care business. Specifically, we understand that most managed care plans have multiple relationships with their contractors and subcontractors for the provision of services for various product lines, including non-federal HMOs, preferred provider organizations (PPOs) and point of service networks. Consequently, although neither a managed care plan receiving a capitated payment from a Federal health care program nor its contractors or subcontractors has an incentive to overutilize items or services or pass additional costs back to the Federal health care programs under the capitated arrangement, we are concerned that a managed care plan or contractor may offer (or be offered) a reduced rate for its items or services in the Federal capitated arrangement in order to have the opportunity to participate in other product lines that do not have stringent payment or utilization constraints. This practice is a form of a practice that has become known as ''swapping''; in the case of managed care arrangements low capitation rates could be traded for access to additional fee-for-service lines of business. We are concerned when these discounts are in exchange for access to fee-for-service lines of business, where there is an incentive to overutilize services provided to Federal health care program beneficiaries.

For example, we would have concerns where an HMO with a Medicare risk contract under Medicare Part C also has an employer-sponsored PPO that includes retirees and requires participating providers to accept a low capitation rate for the Medicare HMO risk patients in exchange for access to the Medicare fee-for-service patients in the PPO. Although in such circumstances the cost to the Medicare program for the risk based HMO beneficiaries will not be increased, there may be increased expenditures for Medicare beneficiaries in the PPO arrangement, since the providers may have an incentive to increase services to the Medicare enrollees in the PPO to offset the discounted rates to the Medicare HMO. Accordingly, such arrangements could violate the anti-kickback statute and should not be protected.

3. Analysis of § 1001.952(t)

a. *Arrangements between eligible managed care organizations and first tier contractors.* Section 1001.952(t)(1) is divided into two parts and sets out the substantive standards that arrangements must meet in order to receive safe harbor protection. Paragraph (t)(1)(i) of this section sets out the standards for arrangements between the eligible managed care organization (EMCO) and any individual or entity that contracts directly with the EMCO. These direct or ''first tier'' contractors are the only parties that are protected by the literal language of section 216 of HIPAA. Accordingly, the regulation treats these first tier contractors differently than individuals or entities that provide health care items or services in accordance with subcontracts with these first tier entities. We refer to these subcontractors as ''downstream'' contractors or providers. Paragraph (t)(1)(ii) of this section sets out the standards which must be met in order for arrangements between first tier contractors and any downstream subcontractor or between successive tiers of downstream subcontractors to be protected.

Under § 1001.952(t)(1)(i)(A), the EMCO and any first tier contractor must have an agreement that is written and signed by the parties, specifies the items and services covered under the agreement, and has a term of at least one year. These requirements are similar to the requirements for written agreements in other safe harbor provisions. In paragraph (1)(i)(A)(IV) of this section, there is a requirement that neither party will receive any additional payment for covered services from the Federal health care programs. This requirement is intended to insure that there is an incentive to control costs by eliminating the ability on the part of the first tier contractor to offset losses incurred through the capitated methodology.

There are three exceptions to this general prohibition on the plan's receipt of additional Federal health care payments. These exceptions, set out in § 1001.952(t)(1)(i)(A)(IV) are:

- HMOs and CMPs that have Medicare cost-based contracts under section 1876 of the Act;
- Federally-qualified HMOs without a HCFA contract; and
- Federally qualified health centers that claim supplemental payments from a Federal health care program.

For Federally-qualified HMOs and Medicare cost-based HMOs/CMPs, the billing arrangement under which they receive additional Federal health program payments must be set forth in

the written agreement. With respect to Federally-qualified HMOs and Medicare cost-based HMOs/CMPs, the language of section 216 of HIPAA expressly requires this exception, since they are ''eligible organizations'' in section 1876 of the Act. The exception for Federally-qualified health centers is beyond the language of section 216. Nevertheless, an exception for Federally-qualified health centers recognizes the special role they play in health care delivery systems in many medically underserved areas. We wish to make clear, however, that the safe harbor protects only the provision of health care items or services by (1) individuals or entities that contract directly with the HMOs and CMPs with cost-based contracts under section 1876 of the Act, or with Federally-qualified HMOs that do not have a risk-based contract with the Medicare program, *i.e.*, first tier providers, or (2) in the case of a Federally-qualified health center, by the health center itself.

As part of this interim final rule, we are soliciting comments concerning coverage of arrangements where a Medicaid managed care plan or an individual or entity under such a plan bills another Federal health care program on a fee-for-service basis for a person that is dually eligible for Medicare and Medicaid. One possibility would be to extend safe harbor protection in instances where (1) the Medicaid plan bills the Federal health care program; (2) the individual or entity is paid by the Medicaid plan in the same amount and in the same way as for those enrollees who are not subject to the coordination of benefits; and (3) neither the plan nor the individual or entity otherwise shifts the burden of such an arrangement to the extent that increased payments are claimed from a Federal health care program.

The last two standards in § 1001.952(t)(1)(i) insure that the discounts by the providers do not increase the risk of overutilization or increased costs in other Federal health care programs. As explained in the overview section, this safe harbor does not protect situations where one party gives or receives a discount or other remuneration in return for or to induce the provision or acceptance of business (other than that covered by the arrangement) for which payment may be made by the Federal health care programs on a fee-for-service basis. In addition, in accordance with paragraph (1)(i)(C) of this section, the arrangement cannot shift the financial burden to the extent that increased payments are claimed from Federal health care programs.

b. *Arrangements between first tier contractors and downstream contractors.* Except as discussed below, arrangements between a first tier contractor and a downstream contractor, or between successive tiers of downstream contractors, are protected as long as the arrangement is for the provision of health care items or services that are covered by the arrangement between the first tier contractor and the EMCO. In addition, arrangements between the first tier contractor and subcontractor, or between such subcontractors and subcontractors farther downstream, must meet the same requirements as apply to arrangements between EMCOs and first tier contractors.

The one exception to the generally broad safe harbor protection for ''downstream'' providers is for arrangements between providers for health care items or services that are downstream from (1) Federally-qualified health centers receiving supplemental payments, (2) HMOs or CMPs with cost-based contracts under section 1876 of the Act; or (3) Federally-qualified HMOs (unless they are provided in accordance with a risk-based contract under section 1876 of the Act or Medicare Part C). Reimbursement to these entities is not strictly risk-based and presents some risk of overutilization and increased Federal program costs. However, the safe harbor does protect entities that are providing items or services in accordance with a contract or subcontract with Federally-qualified health centers if the health centers do not receive any supplemental payments from the State. In such situations, the Federally-qualified health center has a strong financial incentive to guard against overutilization or excessive costs.

c. *Definitions.* For purposes of § 1001.952(t), we have set forth the definition for several terms. Rather than discuss the definitions in alphabetical order (as they appear in the regulation), they are discussed below in logical order, grouping the definitions that apply to various contracting parties together.

Eligible Managed Care Organization—Eligible managed care organizations are Medicare risk-based or cost-based contractors under section 1876 of the Act, Medicare Part C health plans (except for medical savings accounts and fee-for-service plans), certain Medicaid managed care organizations (as described below), most Programs For All Inclusive Care For The Elderly (PACE) and Federally-qualified HMOs.

Section 1001.952(t)(2)(ii)(C)–(D) identify the Medicaid managed care organizations that fall within the definition of eligible managed care organization. Protected arrangements are those defined in section 1903(m)(1)(A) of the Act that provide or arrange for services for Medicaid enrollees under a contract in accordance with section 1903(m). These plans are paid by the State Medicaid agency on a capitated basis. In addition, the safe harbor provision protects other plans with risk-based contracts with a State agency to provide or arrange for items or services to Medicaid enrollees, provided that contracts are subject to the upper payment limit in 42 CFR 447.361 or any equivalent cap approved by the Secretary.

The safe harbor also protects most PACE programs. These programs provide a capitated amount for medical and certain social services for the elderly. The BBA changed not-for-profit PACE programs from demonstration status to covered services under Medicare and Medicaid. PACE programs that still have demonstration status (*i.e.*, certain for-profit programs) are not protected by this safe harbor.

We are soliciting comments on whether the Department of Defense's TriCare program should also be included within the definition of ''eligible managed care organization'' and, if included, to what extent protection should be granted. The committee statement includes TriCare within the types of organizations that should receive protection through the Department's regulatory authority. However, TriCare is a relatively new health care program for the active status military and their dependents, and has a more complex reimbursement methodology than Medicare risk contracts and retains important elements of cost-based, retrospective methodologies. Accordingly, it is unclear whether there are financial safeguards to control overutilization and limit costs to the Federal Government that are sufficient to warrant per se protection from the anti-kickback statute.

First Tier Contractors—A first tier contractor is an individual or entity that has a contract to provide or arrange for items or services directly with an eligible managed care organization.

Downstream Contractor—A downstream contractor is an individual or entity that provides or arranges for items or services in accordance with a subcontract with either (1) a party that is contracting directly with an EMCO, or (2) another party for the provision or arrangement of items or services that are

covered in accordance with a contract between the parties in (1).

Items and Services—The term ''items and services'' is defined for purposes of this section to mean health care items, devices, supplies or services or those items or services that are reasonably related to such services, such as non-emergency transportation, patient education, attendant services, disease management, case management and utilization review and quality assurance. ''Items and services'' does not include marketing services or any similar pre-enrollment activities. The exclusion of marketing services is not meant to apply to nurse call-in lines or value-added services for current enrollees.

E. Section 1001.952(u)—Price Reductions Offered to Qualified Managed Care Plans

1. Overview

An overview of this new safe harbor, a summary of several major issues that arose during the committee's discussions, and an outline of the new provisions of this safe harbor are set forth below.

While § 1001.952(t) protects certain arrangements based upon the ''status'' of the parties, e.g., designation as an eligible organization for purposes of section 1876 of the Act or participation in the PACE program, § 1001.952(u) provides safe harbor protection for arrangements that qualify under the functional test identified in section 216 of HIPAA, that is, risk-sharing arrangements that place a health care provider under substantial financial risk for the cost or utilization of health care services the provider is obligated to provide.

2. Limitations

Section 216 of HIPAA contains two important qualifications that substantially narrow the universe of arrangements that can potentially qualify for protection using the functional test. The most important constraint is that the provider has to be at substantial financial risk for items or services provided to *Federal health care program* beneficiaries. However, except for providers participating in the Medicare and Medicaid managed care plans that are already covered by the new safe harbor in § 1001.952(t), almost all other providers are reimbursed by Federal health care programs on a fee-for-service basis.

However, according to information presented to the committee, most managed care arrangements that cover Federal health care program beneficiaries and are not paid on a risk basis are employer-sponsored health plans that cover retirees who may also qualify for Medicare. In these managed care arrangements, the participating providers typically submit claims for services provided to enrollees who have primary coverage under Medicare directly to the Medicare carriers and intermediaries and receive reimbursement on a fee-for-service basis. In other words, services to Medicare beneficiaries typically are ''carved out'' of the risk-sharing arrangements these plans have with their participating providers. In accordance with section 216 of HIPAA, these providers are not at ''substantial financial risk'' for the cost or utilization of services they provide to Medicare patients. Therefore, such arrangements do not merit protection under the statutory criteria.

The second major limitation in section 216 is that the providers must be at risk for the cost or utilization of items or services they are ''obligated to provide.'' Many risk sharing arrangements with physicians are based on the cost or utilization of items and services they order but that are actually provided by other entities (e.g., physician bonuses based on the number of hospital admissions). Accordingly, this requirement also substantially narrows the universe of arrangements that could potentially qualify for protection under § 1001.952(u).

Working within these two constraints, the committee determined to protect financial arrangements that:

- Are part of a comprehensive managed care arrangement in which at least fifty percent of the enrollees do not have primary coverage under Medicare.
- Place providers at substantial financial risk for the cost or utilization of health care items and services for all enrollees.
- Use the identical risk and payment methodologies to reimburse providers for services provided to enrollees with primary coverage paid by Federal health care programs as is used for all other enrollees. In other words, payments from the plan to its providers must be the same for identical items or services provided to people with similar health status.
- Allow payment differentials only when they are related to utilization patterns and/or costs of providing items or services to the relevant population.

3. Major Issues

a. *Definition of an ''organization''.* The statutory language exempts ''remuneration between an organization and an individual or entity.'' Some committee members believed the term ''organization'' could refer to any entity that provides health care services. However, other committee members were concerned that if the term ''organization'' meant any health care entity or individual, it would be easy for two parties to camouflage an illegal kickback arrangement as a risk sharing arrangement that could meet the requirements of the safe harbor. For example, the entity paying the kickback could agree to a capitation payment below fair market value for one service or group of patients, i.e., the ''remuneration,'' in exchange for referrals of fee-for-service patients. The scheme would be a variant of providing a deep discount on a good not reimbursable by Medicare to induce the purchase of other goods that are reimbursable by Medicare. We have previously stated that such arrangements potentially implicate the anti-kickback statute (61 FR 2130; January 25, 1996).

The committee members opposed to a broad reading of the term ''organization'' contended that the term in section 216 of HIPAA had to be read in context of the entirety of section 216. Under their reading, the term ''organization'' referred back to the term ''eligible organization,'' which preceded it in the same sentence, and should be construed consistent with that term. In other words, an ''organization'' in section 216 of HIPAA should have many of the characteristics of an ''eligible organization'' under section 1876 of the Act. The committee statement, as a whole, reflects this view.

Accordingly, in order to qualify under § 1001.952(u), the risk sharing arrangement must be part of a comprehensive managed care plan. We use the term ''qualified managed care plan'' (QMCP) to describe such plans. These plans must be health plans, as defined in current safe harbor regulations (§ 1001.952(l)(2)), and provide a comprehensive range of health services. In addition, a QMCP must include certain elements in its arrangement with providers to assure that the health care services are managed, including utilization review, quality assurance and grievance procedure requirements. These requirements are derived from the current regulatory requirements for ''eligible organizations'' under section 1876 of the Act. Some of the representatives at the negotiating sessions expressed concern that while some of a QMCP's arrangements with providers will meet the above requirements, others will not. The committee concluded that those

arrangements that meet the requirements could receive protection under the safe harbor, even though the other arrangements could not.

Further, the committee statement, which was adopted as a whole, reflects the view that the QMCP had to be at some financial risk for the cost or utilization of services provided to enrollees. This requirement was especially important because, for the reasons discussed above in section II.E.1 of this preamble, the providers generally are not actually at risk for the items or services being provided to Medicare enrollees. Accordingly, protection for such plans is premised on (1) the plans being at risk for services to their non-Medicare enrollees, and (2) the plans reimbursing providers for items or services to Medicare beneficiaries on the same basis as for other plan enrollees. Given the variety of employer arrangements, the regulations set out two alternative methods by which the QMCP can meet this risk requirement.

The first option is that the QMCP can receive a premium payment that is fixed in advance. This requirement would cover all insurance arrangements in which, by definition, the plan assumes risk. Under this option, 50 percent of the enrollees cannot have primary coverage under Medicare. Alternatively, even where the QMCP is not paid on a premium basis, it can qualify if less than ten percent of the plan's enrollees have primary coverage under Medicare. This alternative will permit many self-funded ERISA plans that provide health care items or services in accordance with arrangements with third party administrators (TPAs) or contracts with insurers for administrative services only (ASOs) to qualify. In these arrangements, an employer pays the TPA or ASO separately for administering the plan and retains responsibility for payments to the providers. In such arrangements, the TPA or ASO may not have a financial incentive to control utilization or costs. Moreover, because the rule requires the providers to reassign any proceeds from Federal health care programs to the employer, the employer may actually profit on services to Medicare beneficiaries. By limiting Federal health care beneficiaries to less than 10 percent of total enrollment, the regulations substantially limit the ability of the employer to offset costs for its employees with Medicare reassignment.

In addition to these requirements, the regulations also would not protect a QMCP that is receiving premiums from setting its premiums based on the number of Federal health care program beneficiaries in the health plan or the amount of services provided to such beneficiaries. Some committee members believed that such a requirement was necessary to prevent employers from receiving lower rates for non-federal health care program beneficiaries because the plan expects to make up the difference on utilization by the Federal health care program beneficiaries for whom they receive fee-for-service payments.

b. *Substantial financial risk.* Developing a definition for ''substantial financial risk'' was one of the most difficult and time consuming tasks for the committee. Several suggestions were offered, and two caucuses were held and developed options. One caucus discussed a numerical approach to the definition, while the other tried to find a non-numerical approach. Much of the discussion over the suggested definitions concerned whether a non-numerical definition could be clear and precise enough for individuals and entities to know definitively whether they met the safe harbor requirements. Suggestions that did not provide enough assurances were discarded, and after some joint discussion, the elements of each approach were combined. The committee statement and these regulations reflect that determination.

For purposes of the rule, the methods to determine substantial financial risk were grouped into three standards:

- The *payment methodology standard* protects certain payment methodologies that are commonly used to place an individual or entity at substantial financial risk, including capitation, percentage of premium arrangements and payments based on certain diagnostic related groupings, so long as the reimbursement is reasonable given the historical utilization patterns and costs for the same or comparable population in similar managed care arrangements. Hybrid payment systems that combine a periodic fixed fee per patient with other incentives, such as withholds and bonuses, should be analyzed under the numeric standard.
- The *numeric standard* includes bonuses and withhold arrangements that meet certain criteria.
- The *physician incentive plan standard* protects arrangements that meet all of the requirements for HCFA's physician incentive plan rules under 42 CFR 417.479.

These provisions are discussed in greater detail in the section-by-section analysis that follows.

c. *Downstream arrangements.* The committee also discussed whether the rule would protect only arrangements between the QMCP and its direct or ''first tier'' contractors, or whether it would also protect arrangements between the first tier contractors and their downstream subcontractors and arrangements between those subcontractors and providers farther downstream. The committee statement, when taken as a whole, reflects the view that, with some exceptions, the rule should protect all written agreements between downstream subcontractors, as well as those between the QMCP and its first tier contractors. However, in order to prevent fee-for-service or cost-based kickbacks disguised as risk-sharing arrangements by contractors that are not at substantial financial risk, subcontractors are only protected if both parties to the subcontract are at substantial financial risk for the items or services covered by the agreement. In other words, if either party to an agreement is not paid on a substantial financial risk basis, the contract is not protected for either party.

Situations in which a subcontractor has an investment interest in its contractor raise other considerations. In such situations, the financial disincentive for overutilization created by a risk sharing arrangement might be offset by a return on the investment interest. Where both parties have to be at substantial financial risk in order to qualify for protection, the parties continue to have the necessary financial risk to protect against overutilization. However, where a first tier contractor has an investment interest in a QMCP, amounts received as a return on investment could offset the controls and safeguards of the risk-sharing arrangement. This result is possible because the QMCP may be receiving fee-for-service payments for services to Medicare enrollees on a reassignment basis. Therefore, the rule does not protect remuneration between a QMCP and a first tier contractor that has an investment interest in the QMCP, unless it qualifies under the large entity investment safe harbor (§ 1001.952(a)).

4. Analysis of § 1001.952(u)

a. *Arrangements between QMCPs and first tier contractors.* In order to qualify for protection, a contractual arrangement must be directly between a QMCP and a first tier contractor. The definition of a QMCP is set forth in § 1001.952(u)(2)(vi). There are three standards that apply to the arrangements between the QMCP and first tier contractors. First, § 1001.952(u)(1)(i)(A) requires that the contracts must be set out in writing and contain certain information, including the payment methodology. These requirements facilitate verification of

compliance with the substantive requirements of the regulation.

Second, § 1001.965(u)(2)(i)(B) makes clear that where a first tier contractor has an investment interest in the QMCP, the investment interest must meet the safe harbor requirements of § 1001.952(a)(1). This condition addresses the concern that the contractor's substantial financial risk may be offset by returns on its ownership interest in the organization and therefore undermine protections against overutilization. We want to emphasize that, while arrangements in which providers have investment interests in a QMCP may not qualify for safe harbor protection, such arrangements do not necessarily violate the anti-kickback statute.

Third, § 1001.952(u)(1)(i)(C) defines ''substantial financial risk'' by four alternative methodologies. The first three methods (paragraphs (u)(1)(i)(C)(I) –(III)) provides protection for several *payment methodologies* that historically have been used by plans and HMOs to transfer risk to providers: Capitation, percentage of premiums and inpatient reimbursement based on Federal health care program diagnostic related groupings (DRGs). Under any of these methods, the payment amounts must be reasonable given the historical utilization patterns and costs for the same or comparable populations in similar managed care arrangements. We are requesting comments on the extent to which the risk of full capitation is diminished by the purchase of commercial stop loss insurance or contractual provisions regarding the limitation of financial liability.

The exception for DRGs is limited to Federal health care program DRGs, since these are the only DRG methodologies with which we have significant experience and data for Federal health care program beneficiaries. Inpatient psychiatric DRGs are not covered because, based on the experience of the Medicare and Medicaid programs, these groupings are not sufficient to deter unnecessary admissions or to protect patients seeking those services. We emphasize that, although the plan must reimburse providers for items and services to other enrollees using the same DRG system, the amount of payment may vary so long as it is based on adequate utilization and cost data for the covered population that justifies the difference.

The definition of substantial financial risk also includes a *numeric standard* for certain bonus and withhold arrangements (paragraph (u)(1)(i)(C)(IV)). In the case of a physician provider, the requirement for substantial financial risk will also be satisfied if the arrangement places the physician at risk for an amount that exceeds the substantial financial risk threshold of the *physician incentive payment* rule (42 CFR 417.479(f)), and the arrangement is in compliance with the stop-loss and beneficiary survey requirements of 42 CFR 417.479(g). Although the committee statement requires the patient panel size to be less than 25,000 covered lives to meet the substantial financial risk element, we determined that this requirement does not provide significant additional protection and, therefore, it is not included in this rule. A bonus or withhold arrangement can also qualify if the target payment is at least 20 percent greater than the minimum payment for individuals or non-institutional entities, or is at least ten percent greater than the minimum payment in the case of institutional entities, specifically, hospitals and nursing homes. We are requesting data on the appropriateness of different target payment percentages for institutional and non-institutional entities. In addition, we also seek comments on whether additional individuals and entities, such as pharmacy providers, manufacturers and federally qualified health centers, should be considered institutional entities for purposes of this paragraph.

The ''minimum payment'' is defined in § 1001.952(u)(2)(v). Generally, it represents the minimum amount a contractor will receive under a contract, regardless of utilization. In addition, the bonus or withhold must be earned in direct proportion to the ratio of the actual to the target utilization. For example, if the provider's utilization is only 80 percent of the target, the provider receives 80 percent of the difference between the target payment and the minimum payment. This requirement should protect against sham arrangements that provide a penalty or bonus conditioned entirely upon achieving a utilization level that is unreasonable. Finally, in calculating the substantial financial risk percentage, the target payment and the minimum payment must both include any bonus for performance (*e.g.*, timely submission of paperwork, continuing medical education, meeting attendance) that is given to at least 75 percent of the participating individuals or entities who are paid a performance bonus based on the same bonus structure under the arrangement. This requirement is necessary to prevent plans from reallocating their compensation to performance bonuses, thereby increasing the apparent percentage of risk on the remaining compensation. In year one of an arrangement, it is not necessary to include the performance bonus in the substantial financial risk calculation.

Section 1001.952(u)(1)(i)(D) provides that the QMCP (or, in the case of a self-funded ERISA plan, the employer) must bill the Federal health care programs directly for covered services and compensate the provider for such services on the same basis as services to similar enrollees without primary coverage from a Federal health care program. Two examples of such arrangements are (1) staff model HMOs where the physicians are salaried, and (2) a plan that, in accordance with a reassignment agreement, bills Medicare for Part B services and pays the provider under the same bonus arrangement applicable to other enrollees. Because Medicare requires hospitals to claim payment directly, the rule is applicable where a hospital submits claims directly to a Federal health care program on a DRG basis and the plan pays the hospital for the plan's other enrollees using the same methodology.

Section 1001.952(u)(1)(i)(E) does not protect parties to a contract from trading discounted business for more remunerative fee-for-service business.

b. *Arrangements with downstream contractors.* Section 1001.952(u)(1)(ii) provides that subcontracting arrangements between first tier contractors and downstream contractors (and any arrangements with providers farther downstream) are protected if both parties are paid in accordance with one of the substantial financial risk methodologies identified in this section. This provides assurances that both parties have a financial incentive to control utilization. In addition, the individual or entity providing items or services in accordance with the contract must be paid for items and services to Federal health care program beneficiaries in the same manner as for other enrollees. Finally, as discussed above, the arrangement cannot involve remuneration in return for, or to include the provision or acceptance of other Federal health care program business and cannot shift the financial burden of the arrangement to the Federal health care programs.

c. *Definitions.* Most of the defined terms in § 1001.952(u) have the same meaning as those set forth in § 1001.952(t). The additional defined terms are discussed below.

Minimum Payment—The minimum payment is the guaranteed amount that an individual or entity is entitled to receive under a risk-sharing contract for purposes of calculating substantial

financial risk under the numeric standard. The minimum payment is the lowest amount a provider can reasonably be expected to receive based on past or expected performance.

Obligated To Provide—The statute requires individuals or entities to be placed at substantial financial risk for the cost or utilization of services they are ''obligated to provide.'' A strict reading of the statutory language would not include many risk arrangements that are currently used to give incentives to physicians. Accordingly, for purposes of this regulation, the term is defined broadly and includes any items or services (as defined in this regulation) for which the individual or entity is financially responsible, makes referrals, or receives incentives based on the provider, group or health plan's performance.

Qualified Managed Care Plan—As discussed above, the committee statement, which was adopted as a whole, reflects the view that protection should apply to only those risk-sharing arrangements for the provision of health care items or services that were part of an comprehensive managed health care plan. For purposes of these regulations, we have defined such plans as ''qualified managed care plans.'' Section 1001.952(u)(2)(vi) requires that the items and services be provided under agreement by an entity that qualifies as a health plan under § 1001.952(1)(2), and § 1001.952(u)(2)(vi)(A) requires that the QMCP provide a comprehensive range of health services. Section 1001.952(u)(2)(vi)(B) requires that the organization provide or arrange for (1) reasonable utilization goals and a utilization review program; (2) a quality assurance program that promotes the coordination of care, protects against underutilization and specifies patient goals, including measurable outcomes where appropriate; (3) grievance and hearing procedures; (4) protection for its members from incurring financial liability other than copayments and deductibles; and (5) assurances that treatment for Federal health care program beneficiaries is no different than for other enrollees due to their status as Federal health care program beneficiaries. These requirements are derived from current regulations under section 1876 of the Act and assure that basic indicia of a managed care plan exist. Finally, the requirement that there be at least 50 percent non-federal health care program enrollees reduces the likelihood that Federal health care program beneficiaries will receive disparate treatment either in insured or ERISA plans as compared to other enrollees.

Target Payment—The target payment is defined as the fair market value payment consistent with arms-length negotiations that will be earned by an individual or entity depending on the individual or entity's meeting a utilization target or range of utilization targets that are consistent with historical utilization rates for the same or comparable populations in similar managed care arrangements. The utilization target may not be a precise number, but rather a range. In order to protect against undue incentives to underutilize, the rule provides that if a provider's utilization falls below or surpasses the utilization target (whether a fixed number or range), any payment amounts attributable to performance beyond (or below) the utilization target will not be included in the calculation of substantial financial risk. Arrangements where the target payment is set at a level that is unrealistic would always produce the appearance of substantial financial risk and, accordingly, will not be protected.

III. Regulatory Impact Statement

Executive Order 12866, the Unfunded Mandates Reform Act and the Regulatory Flexibility Act

The Office of Management and Budget (OMB) has reviewed this interim final rule in accordance with the provisions of Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and has determined that it does not meet the criteria for a significant regulatory action. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety distributive and equity effects). The Unfunded Mandates Reform Act, Public Law 104–4, requires that agencies prepare an assessment of anticipated costs and benefits on any rulemaking that may result in an annual expenditure by State, local or tribal government, or by the private sector of $100 million or more. In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small businesses, the Secretary must specifically consider the economic effect of rule on small business entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity and available information. Regulations must meet certain standards, such as avoiding unnecessary burden. The safe harbor provisions set forth in this rulemaking are designed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy. In doing so, these regulations impose no requirements on any party. Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement actions under the anti-kickback statute. We believe that any aggregate economic effect of these safe harbor regulations will be minimal and will impact only those limited few who engage in prohibited behavior in violation of the statute. As such, we believe that the aggregate economic impact of these regulations is minimal and will have no effect on the economy or on Federal or State expenditures.

Additionally, in accordance with the Unfunded Mandates Reform Act of 1995, we have determined that there are no significant costs associated with these safe harbor guidelines that would impose any mandates on States, local or tribal governments, or the private sector, that will result in an annual expenditure of $100 million or more, and that a full analysis under the Act is not necessary.

Further, in accordance with the Regulatory Flexibility Act (RFA) of 1980, and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, we are required to determine if this rule will have a significant economic effect on a substantial number of small entities and, if so, to identify regulatory options that could lessen the impact. While these safe harbor provisions may have an impact on small entities, we believe that the aggregate economic impact of this rulemaking should be minimal, since it is the nature of the violation and not the size of the entity that will result in a violation of the anti-kickback statute. Since the vast majority of individuals and entities potentially affected by these regulations do not engage in prohibited arrangements, schemes or practices in violation of the law, we have concluded that these interim final regulations should not have a significant economic impact on a number of small business entities, and that a regulatory flexibility analysis is not required for this rulemaking.

Paperwork Reduction Act

As indicated above, the provisions of these interim final regulations are voluntary and impose no new reporting or recordkeeping requirements on health care providers necessitating clearance by OMB.

IV. Public Inspection of Comments

Comments will be available for public inspection beginning December 10, 1999, in Room 5518 of the Office of Inspector General at 330 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:00 a.m. 4:30 p.m., (202) 619–0089.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare.

Accordingly, 42 CFR part 1001 is amended as follows:

PART 1001—[AMENDED]

1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2)(D),(E) and (F), and 1395hh; and sec.2455, Pub.L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

2. Section 1001.952 is amended by republishing the introductory text; by reserving paragraphs (n) through (s); and by adding new paragraphs (t) and (u) to read as follows:

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

* * * * *

(n)–(s) [Reserved]

(t) *Price reductions offered to eligible managed care organizations.* (1) As used in section 1128(B) of the Act, ''remuneration'' does not include any payment between:

(i) An eligible managed care organization and any first tier contractor for providing or arranging for items or services, as long as the following three standards are met—

(A) The eligible managed care organization and the first tier contractor have an agreement that:

(*1*) Is set out in writing and signed by both parties;

(*2*) Specifies the items and services covered by the agreement;

(*3*) Is for a period of at least one year; and

(*4*) Specifies that the first tier contractor cannot claim payment in any form directly or indirectly from a Federal health care program for items or services covered under the agreement, except for:

(*i*) HMOs and competitive medical plans with cost-based contracts under section 1876 of the Act where the agreement with the eligible managed care organization sets out the arrangements in accordance with which the first tier contractor is billing the Federal health care program;

(*ii*) Federally qualified HMOs without a contract under sections 1854 or 1876 of the Act, where the agreement with the eligible managed care organization sets out the arrangements in accordance with which the first tier contractor is billing the Federal health care program; or

(*iii*) First tier contractors that are Federally qualified health centers that claim supplemental payments from a Federal health care program.

(B) In establishing the terms of the agreement, neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service basis.

(C) Neither party to the agreement shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program.

(ii) A first tier contractor and a downstream contractor or between two downstream contractors to provide or arrange for items or services, as long as the following four standards are met—

(A) The parties have an agreement that:

(*1*) Is set out in writing and signed by both parties;

(*2*) Specifies the items and services covered by the agreement;

(*3*) Is for a period of at least one year; and

(*4*) Specifies that the party providing the items or services cannot claim payment in any form from a Federal health care program for items or services covered under the agreement.

(B) In establishing the terms of the agreement, neither party gives or receives remuneration in return to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service basis.

(C) Neither party shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program.

(D) The agreement between the eligible managed care organization and first tier contractor covering the items or services that are covered by the agreement between the parties does not involve:

(*1*) A Federally qualified health center receiving supplemental payments;

(*2*) A HMO or CMP with a cost-based contract under section 1876 of the Act; or

(*3*) A Federally qualified HMO, unless the items or services are covered by a risk based contract under sections 1854 or 1876 of the Act.

(2) For purposes of this paragraph, the following terms are defined as follows:

(i) *Downstream contractor* means an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between an eligible managed care organization and the first tier contractor.

(ii) *Eligible managed care organization*[1] *means*—

(A) A HMO or CMP with a risk or cost based contract in accordance with section 1876 of the Act;

(B) Any Medicare Part C health plan that receives a capitated payment from Medicare and which must have its total Medicare beneficiary cost sharing approved by HCFA under section 1854 of the Act;

(C) Medicaid managed care organizations as defined in section 1903(m)(1)(A) that provide or arrange for items or services for Medicaid enrollees under a contract in accordance with section 1903(m) of the Act (except for fee-for-service plans or medical savings accounts);

(D) Any other health plans that provide or arrange for items and services for Medicaid enrollees in accordance with a risk-based contract with a State agency subject to the upper payment limits in § 447.361 of this title or an equivalent payment cap approved by the Secretary;

(E) Programs For All Inclusive Care For The Elderly (PACE) under sections 1894 and 1934 of the Act, except for for-profit demonstrations under sections 4801(h) and 4802(h) of Pub. L. 105–33; or

(F) A Federally qualified HMO.

(iii) *First tier contractor* means an individual or entity that has a contract directly with an eligible managed care organization to provide or arrange for items or services.

(iv) *Items and services* means health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency

[1] The eligible managed care organizations in paragraphs (u)(2)(ii)(A)–(F) of this section are only eligible with respect to items or services covered by the contracts specified in those paragraphs.

transportation, patient education, attendant services, social services (*e.g.*, case management), utilization review and quality assurance. Marketing and other pre-enrollment activities are not ''items or services'' for purposes of this section.

(u) *Price reductions offered by contractors with substantial financial risk to managed care organizations.* (1) As used in section 1128(B) of the Act, ''remuneration'' does not include any payment between:

(i) A qualified managed care plan and a first tier contractor for providing or arranging for items or services, where the following five standards are met—

(A) The agreement between the qualified managed care plan and first tier contractor must:

(*1*) Be in writing and signed by the parties;

(*2*) Specify the items and services covered by the agreement;

(*3*) Be for a period of a least one year;

(*4*) Require participation in a quality assurance program that promotes the coordination of care, protects against underutilization and specifies patient goals, including measurable outcomes where appropriate; and

(*5*) Specify a methodology for determining payment that is commercially reasonable and consistent with fair market value established in an arms-length transaction and includes the intervals at which payments will be made and the formula for calculating incentives and penalties, if any.

(B) If a first tier contractor has an investment interest in a qualified managed care plan, the investment interest must meet the criteria of paragraph (a)(1) of this section.

(C) The first tier contractor must have substantial financial risk for the cost or utilization of services it is obligated to provide through one of the following four payment methodologies:

(*1*) A periodic fixed payment per patient that does not take into account the dates services are provided, the frequency of services, or the extent or kind of services provided;

(*2*) Percentage of premium;

(*3*) Inpatient Federal health care program diagnosis-related groups (DRGs) (other than those for psychiatric services);

(*4*) Bonus and withhold arrangements, provided—

(*i*) The target payment for first tier contractors that are individuals or non-institutional providers is at least 20 percent greater than the minimum payment, and for first tier contractors that are institutional providers, i.e., hospitals and nursing homes, is at least 10 percent greater than the minimum payment;

(*ii*) The amount at risk, *i.e.*, the bonus or withhold, is earned by a first tier contractor in direct proportion to the ratio of the contractor's actual utilization to its target utilization;

(*iii*) In calculating the percentage in accordance with paragraph (u)(1)(i)(C)(*4*)(*i*) of this section, both the target payment amount and the minimum payment amount include any performance bonus, *e.g.*, payments for timely submission of paperwork, continuing medical education, meeting attendance, etc., at a level achieved by 75 percent of the first tier contractors who are eligible for such payments;

(*iv*) Payment amounts, including any bonus or withhold amounts, are reasonable given the historical utilization patterns and costs for the same or comparable populations in similar managed care arrangements; and

(*v*) Alternatively, for a first tier contractor that is a physician, the qualified managed care plan has placed the physician at risk for referral services in an amount that exceeds the substantial financial risk threshold set forth in 42 CFR 417.479(f) and the arrangement is in compliance with the stop-loss and beneficiary survey requirements of 42 CFR 417.479(g).

(D) Payments for items and services reimbursable by Federal health care program must comply with the following two standards—

(*1*) The qualified managed care plan (or in the case of a self-funded employer plan that contracts with a qualified managed care plan to provide administrative services, the self-funded employer plan) must submit the claims directly to the Federal health care program, in accordance with a valid reassignment agreement, for items or services reimbursed by the Federal health care program. (Notwithstanding the foregoing, inpatient hospital services, other than psychiatric services, will be deemed to comply if the hospital is reimbursed by a Federal health care program under a DRG methodology.)

(*2*) Payments to first tier contractors and any downstream contractors for providing or arranging for items or services reimbursed by a Federal health care program must be identical to payment arrangements to or between such parties for the same items or services provided to other beneficiaries with similar health status, provided that such payments may be adjusted where the adjustments are related to utilization patterns or costs of providing items or services to the relevant population.

(E) In establishing the terms of an arrangement—

(*1*) Neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the arrangement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis; and

(*2*) Neither party to the arrangement shifts the financial burden of such arrangement to the extent that increased payments are claimed from a Federal health care program.

(ii) A first tier contractor and a downstream contractor, or between downstream contractors, to provide or arrange for items or services, as long as the following three standards are met—

(A) Both parties are being paid for the provision or arrangement of items or services in accordance with one of the payment methodologies set out in paragraph (u)(1)(i)(C) of this section;

(B) Payment arrangements for items and services reimbursable by a Federal health care program comply with paragraph (u)(1)(i)(D) of this section; and

(C) In establishing the terms of an arrangement—

(*1*) Neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the arrangement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis; and

(*2*) Neither party to the arrangement shifts the financial burden of the arrangement to the extent that increased payments are claimed from a Federal health care program.

(2) For purposes of this paragraph, the following terms are defined as follows:

(i) *Downstream contractor* means an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between a qualified managed care plan and the first tier contractor.

(ii) *First tier contractor* means an individual or entity that has a contract directly with a qualified managed care plan to provide or arrange for items or services.

(iii) *Is obligated to provide* for a contractor refers to items or services:

(A) Provided directly by an individual or entity and its employees;

(B) For which an individual or entity is financially responsible, but which are provided by downstream contractors;

(C) For which an individual or entity makes referrals or arrangements; or

(D) For which an individual or entity receives financial incentives based on

its own, its provider group's, or its qualified managed care plan's performance (or combination thereof).

(iv) *Items and services* means health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. Marketing or other pre-enrollment activities are not ''items or services'' for purposes of this definition in this paragraph.

(v) *Minimum payment* is the guaranteed amount that a provider is entitled to receive under an agreement with a first tier or downstream contractor or a qualified managed care plan.

(vi) *Qualified managed care plan* means a health plan as defined in paragraph (l)(2) of this section that:

(A) Provides a comprehensive range of health services;

(B) Provides or arranges for—

(*1*) Reasonable utilization goals to avoid inappropriate utilization;

(*2*) An operational utilization review program;

(*3*) A quality assurance program that promotes the coordination of care, protects against underutilization, and specifies patient goals, including measurable outcomes where appropriate;

(*4*) Grievance and hearing procedures;

(*5*) Protection of enrollees from incurring financial liability other than copayments and deductibles; and

(*6*) Treatment for Federal health care program beneficiaries that is not different than treatment for other enrollees because of their status as Federal health care program beneficiaries; and

(C) Covers a beneficiary population of which either—

(*1*) No more than 10 percent are Medicare beneficiaries, not including persons for whom a Federal health care program is the secondary payer; or

(*2*) No more than 50 percent are Medicare beneficiaries (not including persons for whom a Federal health care program is the secondary payer), provided that payment of premiums is on a periodic basis that does not take into account the dates services are rendered, the frequency of services, or the extent or kind of services rendered, and provided further that such periodic payments for the non-Federal health care program beneficiaries do not take into account the number of Federal health care program fee-for-service beneficiaries covered by the agreement or the amount of services generated by such beneficiaries.

(vii) *Target payment* means the fair market value payment established through arms length negotiations that will be earned by an individual or entity that:

(A) Is dependent on the individual or entity's meeting a utilization target or range of utilization targets that are set consistent with historical utilization rates for the same or comparable populations in similar managed care arrangements, whether based on its own, its provider group's or the qualified managed care plan's utilization (or a combination thereof); and

(B) Does not include any bonus or fees that the individual or entity may earn from exceeding the utilization target.

Dated: February 11, 1999.

June Gibbs Brown,

Inspector General.

Approved: June 8, 1999.

Donna E. Shalala,

Secretary.

[FR Doc. 99–29988 Filed 11–18–99; 8:45 am]

BILLING CODE 4150–04–P

Federal Register

Friday
November 19, 1999

Part V

Department of Health and Human Services

Office of Inspector General

42 CFR Part 1001

Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0991–AA66 (Also incorporating RIN 0991–AA74)

Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Final rule.

SUMMARY: This final rule serves both to add new safe harbor provisions under the Federal and State health care programs' anti-kickback statute, as authorized under section 14 of Public Law 100–93, the Medicare and Medicaid Patient and Program Protection Act of 1987, and to clarify various aspects of the original safe harbor provisions now codified in 42 CFR part 1001 (originally proposed in RIN 0991–AA74). Specifically, this final rule modifies the original set of final safe harbor provisions codified in 42 CFR 1001.952 to give greater clarity to that rulemaking's original intent. In addition, this final rule sets forth an expanded set of safe harbor provisions designed to protect additional payment and business practices from criminal prosecution or civil sanctions under the anti-kickback provisions of the statute.

EFFECTIVE DATE: This rulemaking is effective November 19, 1999.

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SUPPLEMENTARY INFORMATION:

I. Background

Section 1128B(b) of the Social Security Act (the ''Act'') (42 U.S.C. 1320a–7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursable under the Federal or State health care programs. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to 5 years. Violations of the anti-kickback statute may also result in the imposition of a civil money penalty (CMP) under section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)) or program exclusion under section 1128 of the Act (42 U.S.C. 1320a–7).

The types of remuneration covered specifically include kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. In addition, prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration intended to induce the purchasing, leasing or ordering, or arranging of any good, facility, service, or item paid for by Federal or State health care programs.

Establishing the Original Safe Harbors

Since the statute on its face is so broad, concern had been expressed that some relatively innocuous commercial arrangements were technically covered by the statute and therefore were subject to criminal prosecution. As a response to the above concern, the Medicare and Medicaid Patient and Program Protection Act (MMPPPA) of 1987, section 14 of Public Law 100–93, specifically required the development and promulgation of regulations, the so-called ''safe harbor'' provisions, designed to specify various payment and business practices which, although potentially capable of inducing referrals of business under the Federal and State health care programs, would not be treated as criminal offenses under the anti-kickback statute. The OIG safe harbor provisions have been developed ''to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements.'' [1] Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement action under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks.

On July 29, 1991, we published in the **Federal Register** the 1991 final rule (56 FR 35952) setting forth various safe harbor provisions to the Medicare and Medicaid anti-kickback statute. The rulemaking was authorized under section 14 of Public Law 100–93, MMPPPA of 1987, and specified certain payment practices that will not be subject to criminal prosecution under section 1128B(b) of the Social Security Act (42 U.S.C. 1320a–7b(b)), and that will not provide a basis for exclusion from Medicare or the State health care programs under section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)). The initial final rulemaking established ''safe harbors'' in ten broad areas: investment interests, space rental, equipment rental, personal services and management contracts, sales of practices, referral services, warranties, discounts, employees, and group purchasing organizations. However, in giving the Department the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the regulations to be evolving rules that would be updated periodically to reflect changing business practices and technologies in the health care industry.

[1] 56 FR 35952; July 21, 1991.

Establishing Additional Safe Harbors

The public comments in response to the original proposed rule establishing the safe harbor provisions contained suggestions for the consideration and adoption of additional safe harbor provisions under 42 CFR 1001.952. As a result of those comments, on September 21, 1993, the OIG published a proposed rule (58 FR 49008) (the ''1993 proposed rule'') formally requesting public comments on seven new areas of safe harbor protection under the anti-kickback statute, as well as proposed modifications to the existing safe harbor for sales of practices. The proposals for new safe harbors addressed investment interests in rural areas; ambulatory surgical centers; group practices; practitioner recruitment; obstetrical malpractice insurance subsidies; referral agreements for specialty services; and cooperative hospital service organizations described in section 501(e) of the Internal Revenue Code.

Clarifying the Original Safe Harbor Provisions

After publication of the 1991 final rule, the OIG became aware of a limited number of issues that had created uncertainties for health care providers trying to comply with the original safe harbor provisions, and of certain instances where our intent, either to protect or preclude protection for particular business arrangements, was not fully reflected in the text of the regulation, even though it was reflected in the preamble. As a result, the OIG developed and published a new notice of proposed rulemaking on July 21, 1994 (59 FR 37202) (the ''1994 proposed clarifications'') intended to modify the text of 1991 final rule to conform to the rulemaking's original intent. The clarifications contained in the proposed rule did not represent an attempt to reevaluate the basic judgments that led to the original safe harbors, but rather were designed to protect business practices originally intended to be

protected by making the regulatory language more precise.

Annual Solicitations for Suggestions for Modified and New Safe Harbors

In accordance with section 205 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Pub. L. 104–191), the Department is now required to develop and publish an annual notice in the **Federal Register** formally soliciting proposals for modifying existing safe harbors and promulgating new safe harbors and OIG special fraud alerts. The Department will review the proposals and, in consultation with the Department of Justice (DoJ), consider issuing new or modified safe harbor regulations, where appropriate. On December 31, 1996, we published the first of these notices in the **Federal Register** (61 FR 69060), soliciting public comment regarding ''the development of proposed or modified safe harbor regulations,'' including the pending proposals for new and modified safe harbors (61 FR 69062). We published additional annual notices on December 10, 1997 (62 FR 65050) and December 10, 1998 (63 FR 68223). (These notices are referred to in this preamble collectively as the ''annual solicitations.'') Respondents to the annual solicitations suggested a number of areas for new or modified safe harbor protection; additionally, a number of respondents commented on the 1993 proposed rule and the 1994 proposed clarifications. This rulemaking is based on the comments received in response to the 1993 proposed rule, the 1994 proposed clarifications, and the annual solicitations insofar as the latter addressed the new and modified safe harbor proposals contained in the 1993 proposed rule and the 1994 proposed clarifications. Other suggestions for new and modified safe harbors are under review and will be the subject of annual reports to Congress made as part of the Inspector General's year-end semiannual report, as required by HIPAA.

Shared-Risk Exception

Section 216 of HIPAA created an exception to the anti-kickback statute for certain risk-sharing arrangements and directed the Department to use a negotiated rulemaking process to establish companion regulations. Specifically, section 216 of HIPAA created an exception for certain managed care arrangements, involving remuneration (i) between eligible organizations under section 1876 of the Social Security Act (certain health maintenance organizations and competitive medical plans) and individuals or entities providing items or services and (ii) between any organization and an individual or entity that has a risk-sharing arrangement, if a written agreement places the individual or entity at ''substantial financial risk'' for the cost or utilization of the items or services provided.

On January 22, 1998, the negotiated rulemaking committee comprised of 21 industry representatives, a representative from the DoJ, and an OIG representative representing the Department, reached consensus on a final proposal for two new safe harbors.[2] Issues raised in comments to the 1993 proposed rule and the 1994 proposed clarifications that pertain to matters covered by the two shared-risk exception safe harbors are not considered in this final rulemaking.

II. Summary of Proposed Rules, Response to Public Comments and Summary of Revisions

In response to the 1993 proposed rule and the 1994 proposed clarifications, we received a total of 313 timely-filed public comments on the additional safe harbors proposed rule and 28 timely-filed public comments on the safe harbor clarifications proposed rule from various provider groups, medical facilities, professional and business organizations and associations, medical societies, State and local government entities, private practitioners, and concerned citizens. We received 32 comments in response to the annual solicitations that were relevant to the issues addressed in this rulemaking. A summary of the comments and our responses to those comments follow.

A. General Comments

1. Conformity With Stark Law

Comment: Several commenters urged the OIG to conform existing and proposed safe harbors to the statutory exceptions to section 1877 of the Act, otherwise known as the ''Stark Law.'' These commenters believe that payment arrangements permitted under the Stark Law should be protected under the anti-kickback statute. They argue that it is confusing for the industry to be subject to two separate bodies of fraud and abuse law applicable to arrangements involving physician self-referrals. At minimum, these commenters urge that the safe harbors be made consistent with the Stark exceptions with respect to physician compliance with the anti-kickback statute.

Response: The Stark Law is a civil statute that generally (i) prohibits physicians from making referrals for clinical laboratory or other designated health services to entities in which the physicians have ownership or other financial interests and (ii) prohibits entities from presenting or causing to be presented claims or bills to any individual, third party payor, or other entity for designated health services furnished pursuant to a prohibited referral. (42 U.S.C. 1395nn(a)(1)). The anti-kickback statute, on the other hand, is a criminal statute that prohibits the knowing and willful offer, payment, solicitation, or receipt of remuneration to induce Federal health care program business. Both laws are directed at the problem of inappropriate financial incentives influencing medical decision-making. This similarity notwithstanding, the statutes are different in scope and structural approach. Under the Stark Law, physicians may not refer patients for certain designated health services to entities from which the physicians receive financial benefits, except as allowed in enumerated exceptions. A transaction must fall entirely within an exception to be lawful under the Stark Law. The anti-kickback statute, on the other hand, establishes an intent-based criminal prohibition with optional statutory and regulatory ''safe harbors'' that do not purport to define the full range of lawful activity. Rather, safe harbors provide a means of assuring that payment practices are not illegal. Payment practices that do not fully comply with a safe harbor may still be lawful if no purpose of the payment practice is to induce referrals of Federal health care program business. Because the two statutory schemes are fundamentally different, the conference report for the Stark Law included language clarifying that ''any prohibition, exemption, or exception authorized under this provision in no way alters (or reflects on) the scope and application of the anti-kickback provisions in section 1128B of the Social Security Act'' (H.R. Conf. Rep. 239, 101st Cong., 1st sess. 856 (1989)).

We are mindful that it may sometimes be burdensome for parties to review their arrangements under two separate statutory schemes. However, it would be inappropriate to adjust our safe harbor provisions in a manner that would prejudice enforcement of the anti-kickback statute merely to conform the safe harbors to an exception or prohibition under section 1877 of the Act. This is particularly the case in view of the clear legislative intent to keep

[2] The OIG's interim final rule addressing the safe harbors for shared-risk arrangements is published in today's edition of the **Federal Register.**

enforcement under the anti-kickback statute separate from enforcement under section 1877 of the Act. Moreover, variation between the Stark Law exceptions and anti-kickback safe harbors is reasonable in light of the schematic differences between the two statutes. To the extent the anti-kickback statute and the Stark Law address the same conduct, the Stark Law acts as a structural bar to arrangements that contain a *per se* conflict of interest. However, even if an arrangement passes muster under the Stark Law, it may still constitute a violation of the anti-kickback statute, if the requisite intent to induce referrals is present.

2. Integrated Delivery Systems and Managed Care

Comment: Several commenters urged the OIG to modify existing safe harbors and develop new safe harbors to protect and encourage the development of integrated health care delivery systems and managed care arrangements. For example, several commenters urged the OIG to provide specific safe harbor protection for payments between wholly-owned entities, including parent entities and their wholly-owned subsidiaries. Some commenters questioned whether the anti-kickback statute is an appropriate method of regulating business arrangements in the health care industry, particularly in the context of managed care.

Response: The anti-kickback statute is very broad and potentially covers many managed care arrangements that are common in the marketplace today. However, we have recognized that many of these arrangements do not create the potential for fraud or abuse under the anti-kickback statute and have created safe harbors aimed at those managed care arrangements. Currently, for example, a safe harbor protects certain price reductions offered to health plans (§ 1001.952(m)). In addition, Congress enacted in HIPAA a statutory shared-risk exception for certain managed care plans and arrangements that put individuals or entities at substantial financial risk.[3]

With respect to integrated delivery systems and payments between wholly-owned entities, we have stated previously that the anti-kickback statute is not implicated when payments are transferred within a single corporate entity, for example, from one division to another, and therefore no explicit safe harbor is needed for such payments (56 FR 35983). We recognize that there are many lawful integrated delivery system arrangements and arrangements between wholly-owned entities in the marketplace today and that many of these arrangements may be beneficial to the Federal health care programs and their beneficiaries. We are concerned, however, that integrated delivery systems, including arrangements involving wholly-owned subsidiaries, may present opportunities for the payment of improper financial incentives that result in overutilization of services and increased program costs and that may adversely affect quality of care and patient freedom of choice among providers. This is primarily of concern where payment by the Federal health care programs is on a fee-for-service basis, as may occur, for example, with a hospital's referrals to a wholly-owned home health care agency (see, for example, *Medicare Hospital Discharge Planning*, OEI–02–94–00320 (December 1997)). Accordingly, we do not anticipate providing safe harbor protection for integrated delivery systems and arrangements between wholly-owned entities at this time. The advisory opinion process (42 CFR part 1008) is available for parties wishing to obtain OIG review of their particular integrated delivery or wholly-owned arrangements.

3. Additional Safe Harbors

Comment: Several commenters urged the OIG to demonstrate renewed commitment to issuing clarifying interpretations of the anti-kickback statute in a regular and timely manner.

Response: The OIG recognizes the need to work closely with the industry to combat fraud and abuse in the Federal health care programs through meaningful industry guidance consistent with our law enforcement obligations. As part of HIPAA, the OIG received substantial additional funding for its fraud-fighting efforts. A portion of that funding has been used for a number of industry guidance purposes, including the creation of an Industry Guidance Branch in the Office of Counsel to the Inspector General, which is tasked with issuing advisory opinions and promulgating safe harbor regulations and special fraud alerts. As part of our mandate under HIPAA, we have canvassed the industry through annual notices in the **Federal Register** soliciting public suggestions for new and modified safe harbors and special fraud alerts. The suggestions received in response to those notices, as well as other suggestions received from the industry or generated internally, are under review, and we anticipate further rulemaking periodically in connection with some of these safe harbor suggestions. We have reported to Congress on the status of the suggestions in the OIG semiannual report to be issued shortly. In addition, the ongoing issuance of advisory opinions, model compliance guidance, special fraud alerts and special advisory bulletins is providing the industry with meaningful guidance on the scope and application of the anti-kickback statute in a regular and timely manner.

4. Transition Period

Comment: Several commenters urged the OIG to afford providers who entered into arrangements with a good faith belief that the arrangements did not violate the anti-kickback statute a reasonable grace period to restructure existing arrangements to conform to the final safe harbors contained in these regulations. In particular, several commenters expressed concern that the 1994 clarifications would be interpreted to be retroactive to the date of the original safe harbors, with no provision for ''grandfathering'' arrangements that providers believed in good faith complied with the safe harbors as set forth in the 1991 final rule. For example, these commenters note that it was not clear that only ''health care'' assets could be counted for purposes of qualifying for the large entity investment safe harbor (§ 1001.952(a)(i)). Specifically, one commenter proposed implementation of a one year grace period.

Response: We recognize that many providers have in good faith attempted to structure lawful arrangements under the anti-kickback statute that may not fit squarely within these final safe harbor rules. In this regard, we repeat our response to similar comments in our preamble to the 1991 final rule. There we stated:

> The failure of a particular business arrangement to comply with these provisions does not determine whether or not the arrangement violates the statute because * * * this regulation does not make conduct illegal. Any conduct that could be construed to be illegal after the promulgation of this rule would have been illegal at any time since the current law was enacted in 1977. Thus illegal arrangements entered into in the past were undertaken with a risk of prosecution. This regulation is intended to provide a formula for avoiding risk in the future.
>
> We also recognize, however, that many health care providers have structured their business arrangements based on the advice of an attorney and in good-faith belief that the arrangement was legal. In the event that they now find that the arrangement does not comply fully with a particular safe harbor provision and are working with diligence and good faith to restructure it so that it does comply, we will use our discretion to be fair

[3] See footnote 2.

to the parties to such arrangements. (56 FR 35955).

These same principles apply with respect to arrangements structured in good faith in accordance with the 1991 final rule. Thus, to the extent that parties reasonably believed that they complied with a safe harbor based on the 1991 final rule and work with diligence and good faith to restructure their arrangements so that they comply with the safe harbor as clarified in this final rule, we will exercise our discretion to be fair to the parties. We are not setting a specific ''grace period,'' as we believe that the reasonable time period for restructuring an arrangement will vary depending on the type and complexity of the arrangement.

5. Meaning of Safe Harbors

Comment: Several commenters asked the OIG to clarify that the failure to meet the conditions of a safe harbor does not mean that an arrangement is suspect under the anti-kickback statute. One commenter expressed concern that members of the public view arrangements that do not comply with a safe harbor as suspect arrangements.

Response: The issue of the scope and effect of the safe harbors is important and often misunderstood. We addressed this issue in our preamble to the 1991 final rule:

> This (safe harbor) regulation does not expand the scope of activities that the statute prohibits. The statute itself describes the scope of illegal activities. The legality of a particular business arrangement must be determined by comparing the particular facts to the proscriptions of the statute.
>
> The failure to comply with a safe harbor can mean one of three things. First * * * it may mean that the arrangement does not fall within the ambit of the statute. In other words, the arrangement is not intended to induce the referral of business reimbursable under (a Federal health care program); so there is no reason to comply with the safe harbor standards, and no risk of prosecution.
>
> Second, at the other end of the spectrum, the arrangement could be a clear statutory violation and also not qualify for safe harbor protection. In that case, assuming the arrangement is obviously abusive, prosecution would be very likely.
>
> Third, the arrangement may violate the statute in a less serious manner, although not be in compliance with a safe harbor provision. Here there is no way to predict the degree of risk. Rather, the degree of risk depends on an evaluation of the many factors which are part of the decision-making process regarding case selection for investigation and prosecution. Certainly, in many (but not necessarily all) instances, prosecutorial discretion would be exercised not to pursue cases where the participants appear to have acted in a genuine good-faith attempt to comply with the terms of a safe harbor, but for reasons beyond their control are not in compliance with the terms of the safe harbor. In other instances, there may not even be an applicable safe harbor, but the arrangement may appear innocuous. But in other instances, we will want to take appropriate action. (56 FR 35954)

Thus, it is not true that every arrangement that does not comply with a safe harbor is suspect under the anti-kickback statute, though such arrangements may be suspect in particular circumstances. Parties seeking guidance about their specific arrangements may request an OIG advisory opinion in accordance with the regulations set forth at 42 CFR part 1008.

B. 1994 Clarifications to Existing Safe Harbors

In general, the 1994 proposed clarifications were designed to clarify various aspects of the original safe harbor provisions. Set forth below are a summary of the proposed clarifications for each safe harbor provision, a summary of the final clarifications adopted in this rulemaking, summaries of the public comments received, and our responses to those comments.

1. Investment Interests

Summary of Proposed Clarifications: We proposed five clarifications to the investment interests safe harbor, as follows

- First, we proposed that only assets or revenues related to the furnishing of health care items or services will be counted for purposes of qualifying for either the $50,000,000 asset threshold for ''large entities'' (§ 1001.952(a)(1)) or the 60–40 gross revenue test for ''small entities'' (§ 1001.952(a)(2)(vi)). The purpose of this modification is to make clear our original intent that only assets and revenues derived from health care lines of business will be considered for purposes of qualifying for safe harbor protection.
- Second, we proposed revising the standards that prohibit an entity from loaning funds to an investor to be used to purchase the investor's investment interest in the entity. (§§ 1001.952(a)(1)(iv) and 952(a)(2)(vii)). The revised standard would make clear that the prohibition also includes any such loan from another investor or a person acting on behalf of the entity or any investor.
- Third, we proposed modifying the first investment interest standard to the small entity investment safe harbor (the 60–40 investor test) to allow an alternative to the existing requirement of class-by-class analysis. Under the current rule, ''each class of investments'' must meet the 60–40 investor test. Upon review, we found this class-by-class analysis unnecessarily restrictive. Accordingly, the proposed alternative would allow equivalent classes of equity investment interests to be combined together or equivalent classes of debt investment interests to be combined together (separate from the equity investments) in order to apportion investors into ''untainted'' and ''tainted'' pools for purposes of meeting the 60–40 investor test.
- Fourth, we proposed striking the language ''items or services furnished'' from the 60–40 revenue rule (§ 1001.952(a)(2)(vi)) in the small entity investment safe harbor to make clear that we did not intend for revenues that the joint venture derives from items or services furnished by an investor to the joint venture (such as management services) to be considered tainted for purposes of satisfying the 60–40 revenue test.
- Fifth, we proposed a clarification in the preamble to the 1994 proposed clarification to the effect that an interested investor must obtain his or her investment interest *in the same* way as members of the public (*i.e.*, directly off a registered national securities exchange through a broker) and the investment interest must be the same type of investment interest that is available to the public. In this regard, we stated that there cannot be any side agreements that require stock to be purchased or that restrict in any manner an investor's ability to dispose of the stock. We proposed no change in the language of the existing safe harbor, which states that the investment interest of an interested investor ''must be obtained on terms equally available to the public thorough trading on a registered national securities exchange * * * or on the National Association of Securities Dealers Automated Quotation Service'' (§ 1001.952(a)(1)(ii)).

Summary of the Final Rule: We are adopting the clarifications to the large and small entity investment safe harbors as proposed in the 1994 proposed clarifications and described above, with the following modifications in response to comments received (unless otherwise noted):

- We have added language to § 1001.952(a)(2)(vii) clarifying that, for purposes of the small entity investment safe harbor, loans to an investor may not be made by individuals or entities acting on behalf of the investment entity or any of its investors. This language is the same as language proposed to be added to § 1001.952(a)(1)(iv) in the large entity investment safe harbor in the 1994 proposed clarifications and was

described as applying to the small entity investment safe harbor in the preamble to the 1994 proposed clarifications. It was inadvertently omitted from the regulatory language published in the notice of proposed rulemaking.

- We have revisited the meaning of ''on terms equally available'' in the second standard of the large entity investment safe harbor and have concluded that an investment interest is obtained on equally available terms if it is obtained at the same price as is available to the general public trading on a registered securities exchange through a broker and is not subject to restrictions on transferability.

Comments and Responses

a. Large Entity Investments

Comment: In response to our clarification that only assets or revenues ''related to the furnishing of health care items or services'' will be counted for purposes of qualifying for either the $50,000,000 asset threshold for ''large entities'' or the 60–40 gross revenue test for ''small entities,'' several commenters sought guidance regarding what constitutes ''health care items or services.'' For example, some commenters wondered whether a managed care organization would be considered a health care business if it does not furnish health care services. Some commenters objected to the proposal, arguing that requiring items and services to be health care related would actually increase the incentives for improper referrals. They reason, for example, that a large entity entirely composed of health-care related businesses would be more susceptible to the lure of paying kickbacks for referrals than a diversified entity less dependent on health care derived profits.

Response: By using the term ''health care items or services,'' we mean (i) health care items, devices, supplies, and services and (ii) items or services reasonably related to the furnishing of health care items, devices, supplies, or services, including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review, quality assurance, and practice management services. Marketing services are not included. In this context, we believe that a managed care company would count as a health care related asset for purposes of the large entity investment threshold test and that revenue derived from a managed care company would count as ''tainted'' revenue for purposes of the 60–40 revenue test in the small entity investment safe harbor.

While we agree that diversified assets may, in some circumstances, indirectly minimize financial incentives for referrals from investor referral sources, we continue to believe that arrangements involving ventures between health care businesses and non-health care business pose an increased risk of program abuse. As we stated in the preamble to the 1994 clarifications, ''[i]t would be an obvious sham, inconsistent with our original intent, if a joint venture could merge with a non-health care business and have those non-health care assets, and the revenues derived from that non-health care line of business counted for the purposes of qualifying for safe harbor protection'' (59 FR 37203–37204).

Comment: Several commenters expressed concern about our clarification of the phrase ''on terms equally available to the public'' in the safe harbor condition that describes how interested investors must obtain their investment interests in order to receive safe harbor protection (§ 1001.952(a)(1)(ii)). We indicated that the phrase should be interpreted to mean that the interested investor must obtain his or her investment interest *in the same way* as investors from the general public. Several commenters urged that this interpretation was too narrow and imposed unwarranted limitations on investment in large entities. These commenters argued, for example, that a large entity should be permitted to purchase a physician's practice using stock in addition to cash, provided that the value of the stock plus all other consideration paid to the physician equals the fair market value for the practice. For example, one commenter asked why it would be acceptable for an entity to purchase a practice for $1 million in cash (assuming fair market value to be $1 million), but not to do so for $500,000 in cash and $500,000 worth of stock. These commenters suggest that the phrase ''on terms equally available'' should mean that the stock is not lettered, restricted, subject to side agreements, or otherwise subject to limited transferability. One commenter proposed an alternative safe harbor condition that would deny safe harbor protection to an interested investor's holding of publicly-traded stock that is subject to transfer restrictions that are not applicable to the stock when held by members of the public.

Response: We have two significant concerns regarding interested investors' investments in large entities that are in health care related businesses. First, we are concerned that limited transferability or other restrictions on the sale or disposition of stock may serve to ''lock'' interested investors into specific investments, thereby increasing the incentives for those investors to refer Federal health care program business to the investment entity. Second, we are concerned that interested investors who are potential referral sources for the investment entity not be permitted to obtain their investment interests at insider prices or at prices more favorable than those available to the general public when purchasing stock from a registered national securities exchange through a broker. Such favorable treatment could potentially be disguised remuneration for referrals. For example, we are aware of certain public offerings of health care companies that involve simultaneous acquisitions of physician practices in exchange for stock in the newly-public company, with the stock valued in a manner that results in the selling physician obtaining the stock at a lower price or on more advantageous terms than offered to the public. The economic benefit conferred on the physician in such an arrangement potentially violates the anti-kickback statute if one purpose of the benefit is to reward or induce referrals. The investment would not fall within the large entity investment safe harbor.

Notwithstanding, upon further consideration of this issue, we are persuaded that requiring stock acquired by interested investors to be obtained *in the same way* as the same stock acquired by members of the public imposes an unduly restrictive interpretation on the existing safe harbor language. Accordingly, we are adding language to make clear that an investment interest will not qualify for safe harbor protection as ''obtained on terms equally available to the public'' if (i) the investment interest is subject to restrictions or limited transferability (including side agreements) not applicable to the same investment interest when held by members of the public and/or (ii) the investment interest is not obtained for the same price that is available to the general public when trading on a registered national securities exchange through a broker. Thus, in the example cited by the commenter above, the investment interest would be protected if $1 million is the fair market value for the physician practice (not taking into account the value of any referrals) and the stock obtained by the physician is valued at $500,000 based on the price per share then available to the general public trading on a registered national

securities exchange through a broker. However, the public stock offering described in the preceding paragraph would not be protected.

b. Small Entity Investments

Comment: Some commenters asked that we clarify which investors constitute referral sources for purposes of the small entity safe harbor. One commenter recommended that we amend the small entity safe harbor to make clear that only physicians (using the Medicare program definition of that term) are capable of making referrals or influencing the flow of business. In this commenter's view, the current OIG position that referral source investors may include hospitals and other entities means that safe harbor protection is unavailable for various integrated delivery system models that involve joint ownership and investment. Another commenter requested that we clarify that manufacturers that invest in health care entities and sell products to those entities are rarely in a position to refer patients, and thus should not fall within the pool of ''tainted'' investors for purposes of the investment interests safe harbors.

Response: We continue to believe that the appropriate focus under this safe harbor is the status of the investors and the ability of the investors to make or influence the investment entity's referral stream or level of business activity. Investors that furnish items or services to the entity, as well as investors that refer patients or otherwise generate business for the entity, are ''tainted'' investors doing business with the entity for purposes of the 60–40 investor test. Thus, to iterate the example provided in the preamble to the 1991 final rule, if a durable medical equipment (DME) supplier and hospital enter into a joint venture to furnish DME to patients when they leave the hospital, both the DME supplier and the hospital fit within the category of investors doing business with the entity (56 FR 35968).

We are not persuaded that hospitals, nursing homes, skilled nursing facilities, or other institutions are incapable of influencing referrals of Federal health care program business. To the contrary, we are aware of instances of referrals that are in fact controlled by these institutions' employees or agents. (See, *e.g., Medicare Hospital Discharge Planning,* OEI–02–94–00320 (December 1997); *Special Fraud Alert: Fraud and Abuse in Nursing Home Arrangements with Hospices,* 63 FR 20415 (April 24, 1998)). Similarly, we believe that managed care companies and physician practice plans may control referrals in certain circumstances. We agree, however, that in many circumstances manufacturers that invest in health care entities and sell products to those entities may not be in a position to refer patients to, or generate business for, those entities for purposes of the 60–40 revenue test (§ 1001.952(a)(2)(vi)). However, in other circumstances, investor manufacturers may fall within the pool of ''tainted'' investors, and thus each arrangement must be evaluated on a case-by-case basis. In short, manufacturers may be ''tainted'' investors for purposes of the 60–40 investor test (§ 1001.952(a)(2)(i)), where they are in a position to furnish items or services to the investment entity or to influence the flow of referrals to the entity.

Comment: One commenter who supported our proposal to aggregate similar classes of investment interests sought clarification of the proposed condition that classes of investment interests be ''similar in all material respects'' for purposes of the 60–40 investor test, particularly as the condition applies to debt investment interests. For example, the commenter noted that the OIG is willing to treat general partners' and limited partners' interests as sufficiently similar for safe harbor purposes (56 FR 37204), even though general partner and limited partner interests are not similar in a number of arguably material respects, such as fiduciary obligations and assumption of liability. With respect to debt interests, the commenter questioned whether differing redemption rights would result in otherwise similar classes of debt being deemed too dissimilar to aggregate. Similarly, the commenter questioned whether debt instruments with different interest rates could be aggregated (especially if the different interest rates accurately reflect market rates at the time the instruments issued) and whether secured debt instruments could be aggregated with unsecured debt instruments.

Response: Our use of the phrase ''similar in all material respects'' was not intended to suggest that for purposes of aggregation, classes of investment interests must be similar in all respects that might be material to a partner or to a lender or a borrower, but only that classes of investment interests must be similar in all respects material to the purposes of the safe harbor. The focus is on the potential for remuneration to investors who are existing or potential referral sources; material investment terms are those terms that create, or relate to the creation of, potential value for investors. For example, classes of investment interests may be aggregated where the classes have similar rights with respect to the entity's income and assets, where investors receive equivalent returns in proportion to amounts invested, and, most importantly, where there is no preferential treatment of referral source investors, including, but not limited to, preferences that take effect in the event of a disposition of entity assets.

Comment: One commenter expressed concern about our treatment of general partners for purposes of the 60–40 investor rule. We have previously stated that general partners—who have fiduciary obligations to manage a partnership so as to make a profit and who are liable for losses incurred due to gross mismanagement—provide services to a partnership and are, therefore, ''tainted'' or ''interested'' investors for purposes of the 60–40 investor rule. The commenter observed that this interpretation serves to disqualify many partnerships from safe harbor protection and that our proposal to permit classes of investment interests to be aggregated for purposes of determining compliance with the 60–40 investor rule does not adequately address this issue. According to the commenter, even under our proposed aggregation test, safe harbor protection is only available if general partners hold a minority interest in the partnership, even if the partnership has no potential referral source investors. Thus, for example, a hospital owned entirely by a partnership composed of non-referral source investors would not qualify for safe harbor protection if the general partners owned more than 40 percent of any class of investment interest.

Response: As we explained in our preamble to the 1991 final rule, it would be inappropriate to grant safe harbor protection, for example, to a joint venture composed of a DME supplier and physicians, because all of the owners would be doing business with the joint venture by either furnishing items or services or making referrals (56 FR 35968). We recognize that there may be circumstances, such as those posited by the commenter, where the fact that an investor is furnishing items or services to the investment entity may not pose an increased risk of improper referrals comparable to the risk posed in our DME/physician joint venture example. However, we find that it is not feasible to craft a rule that would clearly distinguish among types of investors furnishing items or services, while excluding potentially abusive arrangements from safe harbor protection.

Distributions to investors in partnerships that have *no* existing or potential referral source investors may not implicate the anti-kickback statute at all, since the crux of the statute is a prohibition on remuneration to induce or reward referrals of Federal health care program business. To the extent the statute is implicated, partnerships that do not comply fully with all safe harbor conditions will have to be evaluated on a case-by-case basis. Our advisory opinion process is also available to parties contemplating such partnerships (42 CFR part 1008).

Comment: Several commenters supported our proposal to change the 60–40 revenue test by striking ''items or services furnished'' (§ 1001.952(a)(2)(vi)). However, these commenters asked for clarification of the term ''business otherwise generated'' as used in the safe harbor standard. We have previously explained that revenue is ''generated'' if it is ''*induced to come to* the joint venture for items or services *by an investor*'' (56 FR 37205) (emphasis in original). These commenters requested that we clarify that ''by an investor'' means by an investor who is a licensed professional with legal authority to order items and services, for instance, an investor with legal authority to refer or induce a person to obtain care from a participating provider.

Response: We disagree that the definition of an investor for these purposes should be as narrow as the commenters suggest. Certain investors that are arguably not ''licensed professionals,'' such as hospitals, long-term care facilities, home health agencies, managed care companies, and physician practice management companies, may be in a position to generate business for an entity in which they have an investment interest and to receive distributions that may be remuneration for that business. We recognize that there may be occasional instances where business is generated by investors who would not ordinarily be considered as potential referral sources. This might occur, for example, if an investor is not in a health care related line of business, but happens to refer friends or relatives to a joint venture entity in which he or she has invested. However, we think that these situations are likely to be infrequent and, in most circumstances, are not likely to generate appreciable revenue.

Comment: As described above, several commenters questioned our clarification that the term ''revenue'' for purposes of the 60–40 revenue test means revenue related to the furnishing of *health care* items or services. In addition, two commenters expressed concern about an example involving radiologists that we used to illustrate our discussion of the revenue rule in the preamble to the 1994 proposed clarifications. Specifically, the example stated that:

> If a radiologist holds an investment interest in an imaging center and reads all the films at the center, his or her reading of the film does not taint all the revenues from the referrals by non-investors. However, we have received a few questions from people who read the 60–40 revenue rule as making such referrals tainted because the investor furnished services at the joint venture.
>
> We emphasize that if a radiologist-investor is reading the film *and* making referrals or otherwise generating business, then the revenues the joint venture derives from that activity would become tainted. For example, revenues would be tainted when a radiologist-investor takes part in a consultation with a non-investor internist, and during that consultation the radiologist recommends a procedure which is performed at the joint venture. (59 FR 37205).

Commenters complained that in light of this example, a radiologist-investor seeking safe harbor protection would essentially be prohibited from practicing medicine, because he or she would be precluded from recommending follow-up procedures. Moreover, the commenters argued that compliance with the example would not be feasible because of the record keeping and administrative burden associated with tracking all recommendations to determine if recommended follow-up studies were later performed at the radiologist-investor's facility. These commenters asked that we clarify our position regarding radiologist-investors.

Response: We continue to be persuaded that it is appropriate and consistent with our original intent that only health care related revenues be counted for purposes of the 60–40 revenue test. The purpose of the test is to limit the number of investor referrals to a safe harbor protected joint venture, thereby minimizing the risk that profit distributions might be disguised payments for investor referrals.

Our use of the example in the preamble to the 1994 proposed clarifications was merely intended to illustrate the difference between providing items and services to an entity (which does not result in ''tainted'' revenue) and generating business for the entity (which does result in ''tainted'' revenue). In retrospect, our focus on radiologists in the example may have led to some confusion about the anti-kickback implications specifically for radiologists' practice of medicine. In the unique circumstances of radiologists, we wish to clarify that the occasional recommendation of additional testing by a radiologist to an attending physician with whom the radiologist has no financial arrangements and pursuant to a *bona fide* medical consultation is not prohibited under the anti-kickback statute. Accordingly, for purposes of the 60–40 revenue test, such consultative recommendations would not ''taint'' revenue derived from tests performed at the joint venture entity as a result of a subsequent referral of the patient by his or her attending physician for the recommended tests.

Comment: One commenter supported our proposed clarification regarding the prohibition on loans from entities or their investors that are used by investors to purchase their investment interests (§ 1001.952(a)(2)(vii)). Another commenter requested that we make clear that we do not intend to prohibit loans from banks or other unrelated parties.

Response: The seventh investment interest standard addressing loans is not intended to apply to loans from banks or other unrelated third parties that are not equity investors in the entity seeking safe harbor protection and that are not acting on behalf of the entity or any of its investors, even if the loan is used in whole or in part by a prospective investor to purchase an investment interest. On the other hand, the safe harbor condition is intended to preclude from protection loan guarantees, collateral assignments or other arrangements made by an investment entity or any of its investors, or by individuals or entities acting on their behalf, to secure a loan from a bank or other unrelated third party, if the loan is used in whole or in part by an investor to obtain an investment interest in the entity.

Comment: The remaining comments to the existing investment interest safe harbors addressed various aspects of the safe harbors not specifically covered by the proposed clarifications. Two commenters argued that the safe harbor's two 60–40 tests unnecessarily limit potential investors for, and referral sources to, legitimate, cost-effective, high-quality health care ventures. In one commenter's view, the 60–40 tests prevent potential joint ventures from attracting necessary capital and cause investors to refrain from using the venture's services, even when the venture offers higher quality, lower prices, or better patient convenience than competing providers. This commenter noted that the two 60–40 tests are particularly problematic in rural and underserved areas, where alternative sources of capital and

alternative providers are often in short supply.

Response: Except as otherwise noted above, we are adopting the proposed clarifications to the investment interests safe harbor as set forth in our 1994 proposed clarifications. Aside from clarifying that ''revenue'' refers to health care related revenue and deleting the phrase ''items or services furnished'' in § 1001.952(a)(2)(vi), we are not persuaded at this time that there is a need to revisit the two 60–40 tests for small entity investments. Elsewhere in this rulemaking, we address a new safe harbor for investments in rural and urban undeserved areas (§ 1001.952(a)(3)) that eliminates the 60–40 revenue test and incorporates a modified 60–40 investor test.

2. Space and Equipment Rental and Personal Services and Management Contracts Summary of Proposed Clarifications

We proposed 2 clarifications to the space and equipment rental and personal services and management contracts safe harbors (§§ 1001.952(b), (c), and (d)). First, we proposed revising these safe harbors expressly to preclude schemes involving the use of multiple overlapping contracts to circumvent the safe harbor requirement that space and equipment rental and personal services and management contracts be for terms of at least 1 year. This requirement was intended to prevent regular renegotiation of contracts based on the volume of referrals or business generated between the parties. Second, we proposed revising these safe harbors to preclude safe harbor protection for health care providers that rent more space or equipment or purchase more services than they actually need as a means of paying for referrals.

Summary of Final Rule: We are adopting the clarifications to the space and equipment rental and personal services and management contracts safe harbors as proposed in the 1994 proposed clarifications and described above, with the following modifications in response to comments received:

- We are substituting the word ''term'' for the word ''period'' in the second condition of each safe harbor to be more consistent with customary business terminology;
- We are replacing the phrase ''legitimate business purpose'' with the phrase ''commercially reasonable business purpose'' in each safe harbor to make clear that the test is not whether a business arrangement is lawful, but whether it serves a commercially reasonable business purpose, that is, whether the space and equipment leased or services purchased have intrinsic commercial value to the lessee or purchaser.

Comments and Responses

Comment: A commenter expressed concern that the safe harbor condition that a lease cover all equipment leased between parties and specify the equipment leased would jeopardize many common commercial equipment leasing transactions. This commenter asserted that manufacturers and lessors typically lease capital equipment to health care providers at different times, but under leases that cover the same time period, in whole or in part. The commenter opined that other safe harbor conditions, including those prescribing aggregate compensation, fair market value, and arms-length negotiations, are sufficient safeguards against abuse.

Response: We recognize that some lawful equipment contracts will not qualify for safe harbor protection and will need to be analyzed on a case-by-case basis. The existence of a safe harbor for a particular set of business arrangements does not jeopardize other types of arrangements under the anti-kickback statute. Many multiple contract arrangements are legitimate business arrangements that do not violate the statute; however, some multiple contract arrangements are essentially shams that operate to reward and encourage referrals. We are unable to provide safe harbor protection for such arrangements, in view of the potential abuse of multiple overlapping contracts described above. The advisory opinion process (42 CFR part 1008) is available to parties seeking individualized legal opinions regarding the legality of their leasing arrangements under the anti-kickback statute.

Comment: One commenter suggested that for purposes of clarity and consistency with customary business terminology we substitute the word ''term'' for the word ''period'' as used in §§ 1001.952(b)(2), (c)(2), and (d)(2).

Response: We agree that substituting the word ''term'' for ''period'' in §§ 1001.952(b)(2), (c)(2), and (d)(2) would provide clarity and consistency in the context of leases and service contracts.

Comment: One commenter approved of our proposal that the aggregate space, equipment, or services contracted for not exceed ''that which is reasonably necessary to accomplish the legitimate business purpose'' of the party renting the space or equipment or purchasing the services. This commenter believed that the clarification would inhibit lessors with greater bargaining power from coercing lessees into contracting for more space than needed to conduct business. However, several commenters suggested that the language of our proposed clarification is ambiguous, duplicative, and confusing, and, in the words of one commenter, would open a ''Pandora's Box of potentially conflicting interpretations.'' For example, one commenter observed that many arrangements in today's health care arena, such as cost-sharing or risk-sharing arrangements, joint research initiatives, and data collection arrangements, may not reflect ''traditional'' business purposes, but are legitimate and reasonable in responding to insurers' growing demands for cost-effectiveness. One commenter recommended replacing the word ''legitimate'' with the word ''reasonable.''

Response: We believe the proposed clarification further ensures that protected leases and personal services contracts will provide for fair market value compensation. However, we agree that the term ''legitimate'' may be misconstrued. Thus, in the final rule we are substituting the phrase ''commercially reasonable business purpose'' for ''legitimate business purpose'' to make clear that the test is not merely whether a business purpose is legal or illegal. The ''commercially reasonable business purpose'' test is intended to preclude safe harbor protection for health care providers that surreptitiously pay for referrals—whether because of coercion or by their own initiative—by renting more space or equipment or purchasing more services than they actually need from referral sources. By ''commercially reasonable business purpose,'' we mean that the purpose must be reasonably calculated to further the business of the lessee or purchaser. In other words, the rental or the purchase must be of space, equipment, or services that the lessee or purchaser needs, intends to utilize, and does utilize in furtherance of its commercially reasonable business objectives. Thus, for example, a space rental contract between a physician and a DME supplier for space in the physician's office that includes extra office space that the DME supplier neither occupies nor uses for its DME business would not be protected by this safe harbor. Nor would the safe harbor protect the lease of more space than would reasonably be rented by a similarly-situated DME supplier negotiating in an arms-length transaction with a non-referral source lessor. Cost-sharing or risk-sharing arrangements, joint research initiatives,

and data collection arrangements may qualify as commercially reasonable business purposes in many circumstances. However, we are aware of abusive arrangements involving contracts with referral sources for data collection services or research projects where the data to be collected or research to be performed have no value to the entity paying for them and are merely pretexts for payments for referrals. Such arrangements do not comply with the safe harbor and are highly suspect under the anti-kickback statute.

Comment: The remaining comments we received regarding clarification of this safe harbor addressed matters not covered by the proposed clarifications. Several commenters described difficulties in meeting the safe harbor for part-time arrangements—including time-share office leases, per use equipment leases, and personal services contracts with hourly compensation—caused by the requirement that the ''aggregate'' contract price be set in advance (§§ 1001.952(b)(5), (c)(5), and (d)(5)). One commenter noted that these types of arrangements typically contain compensation methods that are set in advance and that can be made consistent with fair market value and unrelated to the volume or value of referrals. Along these lines, one commenter suggested that the OIG permit ''aggregate'' payments that are not set in advance, if they are calculated in accordance with specific and predetermined formulas set forth in the written agreement. Similarly, several commenters expressed concern about the impracticality of the requirement that protected contracts specify the exact schedule of intervals for the use of space or equipment or the rendering of services for many part-time or as-needed arrangements.

Response: We continue to believe that both the ''aggregate'' and the ''specific schedule of intervals'' requirements are necessary to ensure that safe harbor protection is not afforded to arrangements that include payments that are adjusted periodically on the basis of the volume or value of referrals or business otherwise generated from a referral source. We recognize that these requirements may raise practical problems for certain providers seeking safe harbor protection for part-time or as-needed arrangements. Nevertheless, we are aware of many instances of abuse in these types of arrangements; therefore, for purposes of granting protection from prosecution, we believe it is appropriate to protect only those arrangements that can meet the safe harbor's strict standards. However, as we have stated numerous times, safe harbors do not define the scope of legal activities under the anti-kickback statute. Part-time, as-needed, and other similar arrangements that cannot fit within the safe harbor may be lawful, if no payments are made, directly or indirectly, to induce referrals of Federal health care program business.

Comment: One commenter sought clarification regarding the effect of a termination provision in a lease or contract in light of the safe harbor requirement that leases or contracts be for at least a 1-year term. This commenter specifically asked whether the 1-year term requirement is satisfied (i) if the lease or contract allows for ''for cause'' termination by either party, or (ii) if the lease or contract permits termination by either party with or without cause upon advance written notice, provided there is a concurrent contractual provision that restricts parties that terminate without cause from entering into any further relationships for the balance of the required 1-year period.

Response: The 1-year term requirement ensures that protected leases or contracts cannot be readjusted frequently based on the number of referrals between the parties. Although not specifically stated in the safe harbor regulation, a ''for cause'' termination clause that (i) specifies the conditions under which the contract may be terminated ''for cause,'' and (ii) operates in conjunction with an absolute prohibition on any renegotiation of the lease or contract or further financial arrangements between the parties for the duration of the original 1-year term would satisfy the 1-year term requirement. We remain concerned, however, that ''without cause'' termination provisions could be used by unscrupulous parties to create sham leases and contracts. This could occur, for example, where the parties enter into an agreement to pay a sum of money upfront for services to be performed over a period of time. Parties could disguise payments for referrals by terminating the agreement without cause after payment, but before performance of any services. A 1-year prohibition on renegotiation or further financial arrangements would be meaningless in such circumstances.

3. Referral Services

Summary of Proposed Clarifications: The referral services safe harbor requires that any fee a referral service charges a participant be ''based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated *by the participants* for the referral service * * *'' (§ 1001.952(f)(2)) (emphasis added). This language created an unintended ambiguity when a referral service tries to adjust its fee based on the volume of referrals *it makes to the participants.* We proposed clarifying that the safe harbor precludes protection for payments from participants to referral services that are based on the volume or value of referrals to, or business otherwise generated by, *either* party for the other party.

Summary of Final Rule: We received one comment in favor of our proposed clarification to the referral services safe harbor and none opposed. We are adopting the proposed clarification as set forth in the 1994 proposed clarifications.

4. Discounts

Summary of Proposed Clarifications: As a general rule, discounts for health care items and services are encouraged under the Federal health care programs so long as the Federal health care programs share in the discount where appropriate, and as appropriate, to the reimbursement methodology. Arrangements in accordance with which Federal programs get less than their proportional share of cost-savings on items or services payable by the programs are seriously abusive. Such arrangements result in the programs being overcharged and are not protected by either the statutory exception or regulatory safe harbor for discounts.

Because of expressed industry uncertainty over what obligations individuals or entities have to meet in order to receive protection under this safe harbor, we proposed clarifying the discount safe harbor by dividing the parties to a discount arrangement into three groups—buyers, sellers, and offerors of discounts—with descriptions of each party's obligations in separate paragraphs. In addition, we proposed clarifying the definition of ''rebate'' for purposes of this safe harbor. A rebate under our proposal would be defined as any discount not given at the time of sale. Consequently, a rebate transaction would not be covered by the safe harbor if it involves a buyer under § 1001.952(h)(1)(iii) that is neither a cost-reporter nor a HMO or CMP, because for such buyers, all discounts must be given at the time of sale.

We also proposed clarifying the scope of safe harbor protection for sellers in situations where buyers have not fully complied with their obligations under the safe harbor provisions. If a seller has done everything that it reasonably could under the circumstances to ensure that the buyer understands its obligation to

report the discount accurately, the seller is protected irrespective of the buyer's omissions. To receive such protection, however, the seller must report the discount to the buyer and inform the buyer of its obligation to report the discount. To emphasize that the seller's obligations require more than perfunctory compliance with the safe harbor, we proposed adding that the seller must inform the buyer ''in an effective manner.'' We also proposed adding a requirement that the seller ''refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.'' Thus, if the seller, in good faith, meets its obligations under the safe harbor and the buyer does not meet its obligations due to no fault of the seller, the seller would receive safe harbor protection. However, when a seller submits a claim or request for payment on behalf of the buyer, the seller must fully and accurately report the discount to the appropriate Federal or State health care program. An offeror of a discount would similarly receive safe harbor protection if it meets all of its safe harbor obligations, but its buyer or seller does not meet its obligations due to no fault of the offeror.

We further proposed clarifying whether any reduction in price offered to a beneficiary could be safe harbored under this regulation. To the extent that a discount is offered to a beneficiary and all other applicable standards in the safe harbor are met, such a discount would receive safe harbor protection. However, discounts to beneficiaries in the form of routine reductions or waivers of any coinsurance or deductible amount owned by the beneficiaries do not meet the safe harbor conditions and are not protected.

The preamble to the 1991 final rule stated that when reporting a discount, one only need report the actual purchase price and note that it is ''net discount.'' However, for purposes of submitting a claim or request for payment, we proposed clarifying that what is necessary is that the value of the discount be accurately reflected in the actual purchase price. It is not necessary to distinguish whether this price is the result of a discount or to state ''net discount.'' Consequently, parties who were uncertain about how or where to report on a particular form the fact that the price was due to a discount need not be concerned with reporting that fact, as long as the actual purchase price accurately reflects the discount.

Finally, we proposed some minor editorial changes that do not affect the substance of the provision, but hopefully make it easier to understand.

Summary of Final Rule: We are adopting the clarifications to the discount safe harbor as proposed in the 1994 proposed clarifications and described above, with the following modifications in response to comments received (unless otherwise noted):

- In paragraphs (h)(2) and (h)(5)(ii), we are changing the words ''furnishes'' to ''supplies'' and ''furnishing'' to ''supplying,'' respectively, to clarify the role of sellers under the discount safe harbor and to avoid confusion with other regulatory uses of the word ''furnishes.''
- We are modifying our proposal that sellers and offerors give buyers ''effective notice'' of their obligations to report discounts by requiring instead that sellers and offerors provide buyers with notice in a manner that is reasonably calculated to give the buyers notice of their reporting obligations, including their obligation to provide information to the Secretary upon request under § 1001.952(h)(1). The intent of this modification is to make clear that safe harbor protection for sellers and offerors who fully comply with the safe harbor conditions is conditioned on the actions of the sellers and offerors, and not on the buyers' compliance.
- We are modifying our proposed definition of a ''rebate'' to include any discount the terms of which are fixed at the time of the sale of the good or service and disclosed to the buyer, but which is not received at the time of the sale of the good or service. This modification will enable us to extend safe harbor protection to certain charge-based buyers and buyers reimbursed on the basis of fee schedules who obtain rebates. We are eliminating the requirement that charge-based buyers report discounts on claims submitted to the Federal programs; however, we are retaining the requirement that such buyers provide documentation of discounts to the Secretary upon request.
- We are clarifying that credits and coupons may qualify for safe harbor protection if they meet all of the safe harbor criteria; however, credits or coupons that are, in essence, cash equivalents are not discounts for safe harbor purposes.
- We are clarifying that, in certain circumstances described in more detail below, discounts on multiple items may qualify as a ''discount'' for safe harbor purposes where the reimbursement methodology for all discounted items or services is the same and where the discount can be fully disclosed to the Federal health care programs and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology.
- We are correcting a technical error in the proposed clarifications by changing the word ''include'' in § 1001.952(h)(5)(ii) to ''induce.''

Comment and Response

Comment: Many commenters questioned the relationship between the regulatory safe harbor for discounts and the statutory exception for discounts, which provides for protection for ''a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program, if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program'' (42 U.S.C. 1320a–7b(b)(3)(A)). In the preamble to the 1991 final rule, we stated that the regulatory safe harbor includes *all* discounts Congress intended to protect under the statutory exception (56 FR 37206). Commenters expressed concern that this statement means that failure to qualify under the discount safe harbor is a statutory violation if items or services payable by a Federal health care program are involved, since intent to induce business is always present in a discount arrangement. Under this interpretation, according to commenters, numerous forms of discount pricing, such as pricing one product dependent on the price of another, discount package pricing, and certain capitation arrangements, would be prohibited without the case-by-case analysis generally afforded other types of arrangements that do not fit squarely within a safe harbor. These commenters also urge that limiting permissible discounts to those that comply with the safe harbor ''freezes'' the health care industry into a particular way of doing business, thereby chilling innovations in discount pricing that could result in reductions in health care costs, especially as the market moves from fee-for-service arrangements to managed care. These commenters argue that Congress did not give the OIG authority to constrict the reach of the statutory exception. One commenter observed that Congress unequivocally stated that practices protected under the safe harbors were to be *in addition* to existing statutory protections (Pub. L. 100–93, section 14(a)), and therefore the regulatory discount safe harbor should create a class of protected practices *in addition* to practices protected under the statutory exception.

Response: As stated in the preamble to the 1994 proposed clarifications, it continues to be our position that the

regulatory safe harbor protects *all* discounts or reductions in price protected by Congress in the statutory exception (see 59 FR 37206). The Secretary is vested with the authority to make and publish rules, not inconsistent with the Social Security Act, necessary to the efficient administration of her functions under the Social Security Act (42 U.S.C. 1302). The anti-kickback statute, including all exceptions thereto, are codified as part of the Social Security Act. Moreover, the regulatory safe harbor expands upon the statutory safe harbor by defining additional discounting practices not included in the statutory exception that are not abusive, such as certain discounts to beneficiaries (other than routine waivers of cost-sharing amounts) that meet all applicable safe harbor standards. In sum, the regulatory safe harbor both incorporates and enlarges upon the statutory exception.

Comment: One commenter questioned the safe harbor exclusion of reductions in price that are available to one payer but not to Medicare or Medicaid (§ 1001.952(h)(3)(iii)), noting that it is unclear how failure to provide a discount to Medicare or Medicaid gives rise to a question under the anti-kickback statute, which prohibits remuneration to induce referrals of items or services payable by a Federal health care program. The commenter further argued that there is no basis in the statutory discount safe harbor for a requirement that Medicare and Medicaid patients receive the same prices as other patients.

Response: The safe harbor excludes from the definition of a protected ''discount'' price reductions that apply to one payer but not to the Federal health care programs. This exclusion is necessary to protect against abusive arrangements in which remuneration in the form of discounts on items or services for private pay patients is offered to a provider to induce referrals of Federal health care program patients. For example, as noted in the preamble to the 1991 final rule, we are aware of clinical laboratories that offer price reductions to physicians for laboratory work for private pay patients on the condition that the physicians refer all of their Medicare and Medicaid business to the laboratory. Such ''swapping'' arrangements, which essentially shift costs to the Federal health care programs, continue to be of concern to this office. We do not believe that Congress intended to except such schemes from the anti-kickback statute. Nor do we believe that Congress intended for the Federal health care programs to pay premium prices and thus serve as *de facto* subsidy programs for other reimbursement systems.

Comment: Several commenters generally supported the clarification of the discount safe harbor to recognize 3 groups: Buyers, sellers and offerors. However, a number of commenters requested further clarification regarding the meaning of ''offeror'' and how an ''offeror'' differs from a ''seller''. Specifically, commenters asked about the application of the ''offeror'' category to wholesalers and other brokers, as well as to managed care plans, group purchasing organizations and preferred provider organizations.

Response: An ''offeror'' may be any individual or entity that provides a discount on an item or service to a buyer, but that is not the seller of the item or service. For example, many pharmaceutical manufacturers sell some or all of their products through wholesalers, which, in turn, sell the products to hospitals, retail pharmacies, HMOs, and other providers. A manufacturer may offer a discount in the form of a rebate to the ultimate purchaser that is in addition to any discount from the wholesaler to the retailer. For purposes of this regulation, the manufacturer would be the ''offeror,'' the wholesaler the ''seller,'' and the retailer the ''buyer.'' While we believe that typically the wholesaler would be the ''seller'' and its retail customer the ''buyer,'' if a wholesaler offers a discount to a retail purchaser that has purchased the discounted product from another party, the wholesaler could qualify as an ''offeror.''

Nothing in these regulations precludes a managed care organization, including a preferred provider organization, from being eligible as an ''offeror'' in accordance with the safe harbor. However, in many situations, discounts offered by managed care organizations will not fit within the scope of the discount safe harbor, because the buyers who obtain the discounts will not be providers of services that claim payment for costs or charges associated with the discounted items or services under a Federal health care program. For example, the recipient of a preferred provider organization discount is typically an employer or other payer or patient. However, some discount arrangements offered by a managed care organization may be eligible for safe harbor protection under the discount safe harbor, provided all conditions of the safe harbor are satisfied. In addition, managed care ''discounts'' are potentially protected by the shared-risk exception (42 U.S.C. 1320a–7b(b)(3)(F)), and the existing safe harbors for managed care arrangements (§§ 1001.952(l) and (m)).

Comment: One commenter objected to the safe harbor's portrayal of the role of ''sellers.'' This commenter maintained that sellers do not generally ''furnish'' items or services, nor do they ''permit'' buyers to take discounts off the purchase price. Rather, sellers sell, lease, transfer, or otherwise arrange for the use of products, in some cases involving discounts or reductions in price. This commenter noted that other OIG regulations define ''furnish'' as referring to items and services provided directly by or under the direct supervision of, or ordered by, a practitioner or other individual, or ordered or prescribed by a physician (either as an employee or in his or her own capacity), a provider, or other supplier of services (see § 000.10). In addition, the preamble to the OIG final rule addressing amendments to the OIG's exclusion and CMP authorities resulting from Public Law 100–93 states that manufacturers who do not receive payment directly or indirectly from Medicare or Medicaid do not ''furnish'' items in the context of that definition (57 FR 3298 and 3300). For consistency and to avoid confusion, the commenter suggests that the term ''furnished'' should be replaced by the term ''supplies.''

Response: To avoid confusion with other regulatory definitions, we agree that the term ''supplies'' should be substituted for ''furnishes'' in §§ 1001.952(h)(2) and (h)(5)(ii).

Comment: Several commenters commented that the proposed language clarifying the seller's obligation to disclose the discount properly to the buyer is beyond the scope of the statutory exception and confuses rather than clarifies the seller's obligations. A number of commenters suggested that the requirement that sellers provide effective notice would lead to mistrust between buyers and sellers and disputes about whether ''effective notice'' was provided. One commenter suggested that the requirement inappropriately saddles a seller with the responsibility of being the buyer's ''brother's keeper.'' Some commenters requested clarification of what qualifies as ''notice.'' Others questioned the intention of the added language requiring sellers to ''refrain from impeding'' the buyer's performance of its obligations. One commenter objected that this requirement imposed an undue burden on sellers, because sellers would have to know all of an individual buyer's specific billing activities and possible obligations in order to be in a position to refrain from doing anything

that could impede the buyer in meeting its obligations.

Response: As we stated in the preamble to the 1991 final rule (56 FR 35958), we believe the statute permits us to interpret statutory terms used in the statutory exceptions, including the phrase ''appropriately reflect'' in the discount exception (also see 42 U.S.C. 1302). We note that the statutory exception does not protect any seller if the purchaser has not appropriately reflected the discount. Thus, the objection based on the statute is misplaced.

With respect to the substance of the comments, the proposed clarification would require that the seller inform the buyer ''in an effective manner'' of the buyer's obligation to report the discount and refrain from doing anything to impede the buyer from fulfilling its obligations. We agree that the phrase ''in an effective manner'' perhaps unintentionally focuses on the buyer's conduct and might inappropriately be interpreted to mean that a seller is only protected when the buyer, in fact, fulfills its obligation to report the discount. This was not our intention. Accordingly, we have decided to modify the language to require the seller to inform the buyer of its obligations ''in a manner that is reasonably calculated to give notice to the buyer.'' We believe this language provides the seller with an objective standard by which to measure the sufficiency of its notice. We are further clarifying that for safe harbor purposes one of the buyer's obligations is to provide information about discounts to the Secretary upon request in accordance with § 1001.952(h)(1).

We are not prescribing a specific form of notice. The form of notice appropriate in particular situations may vary. Our intention in adding the ''refrain from impeding'' standard is to make clear that a seller will only be protected by the safe harbor if it is not complicit in a buyer's noncompliance with its obligations to report discounts accurately to the Federal health care programs. We are not making any change to the requirement that the seller not impede the buyer's compliance because we believe the language is clear. The same standard applies to offerors; they will not be protected by the safe harbor if they are complicit in either buyer or seller noncompliance.

Comment: A number of commenters objected to our bar on safe harbor protection for rebates offered to charge-based providers. Our proposed definition of ''rebate'' defined a rebate as a discount not given at the time of sale. Under our proposed clarification, safe harbor protection would only be extended to charge-based providers for discounts made at the time of sale of a good or service. The commenters point out, for example, that the regulation precludes retail pharmacies and outpatient clinics from being eligible for price reductions on the same basis as hospitals (cost reporters) and other large purchasers (*e.g.*, HMOs). Moreover, the commenters note that there may be situations in which adjustments to previous billings or other errors could result in a rebate. The commenters also maintain that where payment is based on the lesser of actual charges or a fee schedule amount, fee schedules could be adjusted to reflect the availability of volume discounting. The commenters argue that excluding rebates for charge-based providers lacks a statutory basis, since the statutory exception refers to a ''reduction in price obtained by a provider,'' without any reference to *when* the reduction must be obtained. The commenters further argue that there is no sound basis for not protecting delayed discounts to physicians, since we are not requiring physicians to reduce their charges for the amount of a discount, even where there is a separately claimed item. Thus, the commenters urge that rebates be covered so long as the amount is fully disclosed to the Federal health care programs and the other safe harbor conditions are satisfied.

Response: The most important aspect of the discount safe harbor is that the Federal health care programs share in the discount in proportion to the percentage the programs pay of the total cost. Congress intended *only* to protect discounts that could fairly benefit the Federal health care programs. It is our intention in these regulations to ensure that the only discounts protected are those where the Federal programs receive such benefit.

Having considered the comments received about rebates, we have concluded that excluding safe harbor protection for all rebates to charge-based buyers or buyers that are reimbursed based on Federal program fee schedules is unnecessarily restrictive and may prevent the Federal health care programs from realizing indirect benefits that may accrue from rebates to charge-based providers.

Accordingly, we are defining a ''rebate'' for purposes of the safe harbor as a discount, the terms of which are fixed at the time of the sale and disclosed to the buyer at the time of sale, but which is not given at the time of sale. ''Terms'' refers to the methodology that will be used to calculate the rebate (*e.g.*, a percentage of sales or a fixed amount per item purchased during a given period of time). The terms of the rebate must be set at the time of the sale and disclosed to the buyer, even though the exact dollar amount of the rebate may not be known until the rebate is paid. In some circumstances, a rebate may be paid only after some number of successive purchases of particular goods or services; in such circumstances, the terms of the rebate must be fixed and disclosed to the buyer at the time of the first sale of a good or service to which the rebate applies. We are eliminating the safe harbor requirement that charge-based buyers (and sellers if submitting claims on behalf of charge-based buyers) disclose the amount of discounts on claims submitted to the Federal programs. We are retaining the existing requirement that buyers (and sellers submitting claims on their behalf) must provide information documenting the discount upon request of the Secretary.

Comment: The proposed clarifications eliminated a reference to credits and coupons in the definition of a ''discount'' (§ 1001.952(h)(3)). Two commenters expressed concern that this deletion indicated an intent to prohibit safe harbor protection for credits and coupons.

Response: To the contrary, our revised definition of ''discount'' applies to any reduction in the price a buyer who buys directly or through a wholesaler or group purchasing organization is charged for an item or service based on an arms-length transaction, except for certain forms of price reduction expressly not included in the definition (*e.g.*, no cash or cash equivalents, no routine waivers of copayments). If a coupon or credit fits within the definition of a discount, it is included within the safe harbor (assuming all safe harbor conditions are satisfied). However, we did not intend to protect credits or coupons that are merely surrogate cash payments, such as credits or coupons that can be used like cash to purchase unspecified goods or services from the seller or offeror. Thus, a coupon good for a reduced price on a designated item could be included in the definition, so long as it meets all of the other requirements of the regulation; however, a coupon good for a certain dollar amount off any goods sold by the seller is not included in the definition. We are, therefore, adding clarifying language to the definition of ''discount'' to make clear that cash equivalents are not discounts for purposes of the safe harbor.

Comment: One commenter objected to a ''discount'' for purposes of the safe harbor being limited to discounts offered to buyers who buy directly or

through wholesalers or group purchasing organizations. This commenter urged that this limitation fails to accommodate new distribution arrangements, many of which contribute to purchasing economies. For example, hospitals, physicians or ambulatory surgical centers may buy items and services through HMOs or other brokering-type suppliers.

Response: In general, if a discount is negotiated with a *bona fide* seller of the item or service, including an entity that aggregates provider demand to obtain access to volume discounts, in accordance with an arms-length transaction, and if the discount otherwise meets all safe harbor requirements, we believe that the discount would come within the safe harbor definition of discount. However, there may be arrangements that do not fit the definition where access to a seller's favorable discount rates is itself an inducement or reward for referrals, *e.g.*, providing certain physician practices access to a hospital's employee health benefits plan in order to reduce the physician's employee insurance costs.

Comment: Several commenters expressed concern about the exclusion from the definition of ''discount'' of price reductions furnished on one good or service without or at a reduced charge to induce the purchase of a different good or service. These commenters assert that this restriction was intended to preclude furnishing a good at a reduced price in exchange for any agreement to buy a good which was reimbursed under a different reimbursement methodology, in such a way that discounts would not be passed along to the Medicare program. For example, the safe harbor was not intended to protect a discount on hospital supplies covered by a Diagnostic Related Group (DRG) payment in exchange for the purchase at the full price of capital equipment separately reimbursed by Medicare on a reasonable cost basis in accordance with a hospital's cost report. Nor was it intended to protect a discount earned on products reimbursed by Medicare but applied to products reimbursed by non-Medicare payers. However, these commenters argue that the safe harbor should not exclude discounts on multiple products when the net value of the discounts could be properly reported to, and benefit, the Medicare program. For example, commenters believe that safe harbor protection should be available for a discount to a hospital for sterile gauze pads in exchange for the purchase of surgical tape, both of which are included in the hospital's DRG payment and recorded on the hospital's cost report as routine costs not separately reimbursable. These commenters expressed concern that the discount safe harbor's limitation on discounts for bundled or multiple items or services fails to recognize the diversity of cost controls inherent in such reimbursement methodologies as DRGs; physician payment under the RBRVS system; national limitation amounts for clinical laboratory tests; fee schedules for DME, prosthetics, orthotics, and other supplies; and fixed rates for ASCs. Finally, commenters noted that by restricting discounts on multiple items, the safe harbors may prevent the Federal health care programs from benefitting from purchasing economies that result from volume purchasing and group discounts.

Response: We agree that one purpose of the limitation on discounts for bundled items or services is to preclude protection for discounts that do not benefit the Federal health care programs, but which are used to induce purchases of other products for which the Federal health care programs pay the full price. These discounts are problematic, because they shift costs among reimbursement systems or distort the true costs of all items. As a result, it may be difficult for the Federal health care programs to determine proper reimbursement levels. (See 56 FR 35987, for example, citing the example of the development of accurate pricing data for intraocular lenses.)

However, we are persuaded that in certain circumstances, discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the programs through lower costs or charges achieved through volume purchasing and other economies of scale. Such circumstances exist where the goods and services are reimbursed by the same Federal health care program in the same manner, such as under a DRG payment.

Comment: Several commenters questioned our intent in changing certain language in the definition of discount from ''in exchange for any agreement to buy a different good or service'' to ''to include (induce) the purchase of a different good or service.'' (See § 1001.952(h)(5)(ii)).

Response: We changed this language to be consistent with the anti-kickback statute, which prohibits inducements to refer Federal health care program business, even if there is no actual referral made or agreement to refer. We are correcting an editorial error in the proposed rule, which incorrectly used the word ''include'' instead of ''induce'' in § 1001.952(h)(5)(ii).

5. Sham Transactions or Devices

Summary: We proposed a new provision to clarify that any arrangement entered into or employed for the purpose of appearing to fit within a safe harbor when the substance of the arrangement is not accurately reflected by its form will be disregarded, and the substance of the arrangement will determine whether safe harbor protection is warranted.

Comment: Although one commenter supported the proposed sham transactions rule, many commenters objected to it. These commenters argued that the proposed sham transactions rule was vague, lacked clear objective criteria, and did not provide any examples of sham transactions.

Response: Upon further consideration, we have decided to withdraw this proposal. We emphasize, however, that for purposes of determining compliance with the safe harbors, we will evaluate both the form and substance of arrangements. To be protected, the form must accurately reflect the substance. As we have explained in the context of space and equipment rentals:

> If a sham contract is entered into, which on paper looks like it complies with these provisions, but where there is no intent to have the space or equipment used or the services provided, then clearly we will look behind the contract and find that in reality payments are based on referrals. Thus, these contracts would not be protected under these provisions. (56 FR 35972)

This same general principle would apply in determining compliance with other safe harbors.

C. 1993 Proposed Safe Harbors

The 1993 proposed rule set forth new safe harbor regulations in the subject areas described below. Each description includes a summary of the proposed rule; a summary of the final rule, including a summary of significant changes between the proposed and final rules; and a summary of comments received and our responses.

1. Investment Interests in Underserved Areas

Summary of Proposed Rule: It had come to our attention that it is difficult for entities located in many rural areas to comply with the two 60–40 tests set forth in the ''small entity'' investment interest safe harbor. The first 60–40 rule (§ 1001.952(a)(2)(i)) requires that no more than 40 percent of the investment interests of the entity be held by

investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity (the ''60–40 investor rule''). The second 60–40 rule (§ 1001.952(a)(2)(vi)) requires that no more than 40 percent of the gross revenue of the entity may come from referrals or business otherwise generated from investors (the ''60–40 revenue rule''). Entities located in rural areas may have an especially difficult time complying with these two standards, because in many cases physicians may be the primary sources of capital in the area, and those physicians may have no alternative facility to which they can refer.

Consequently, we proposed an additional safe harbor for investments in entities located in rural areas that would have eliminated the two 60–40 rules. We proposed defining the rural areas included in the safe harbor in accordance with the standards set by the Office of Management and Budget (OMB) and used by the Bureau of the Census. We solicited comments on the appropriateness of this definition of rural area. We stressed that the method for designating rural areas must ensure that this safe harbor only protects entities that truly serve a rural population. We suggested that one alternative would be to adopt the definition of ''rural'' found at 42 CFR 412.62(f)(1)(ii), which is the definition used by HCFA in its DRG reimbursement rules. We proposed leaving in place the remaining six standards for small entity investments for purposes of the new safe harbor. These six standards provide substantial assurances against abuse, and we had not been apprised of any particular difficulty that rural entities were experiencing with these standards.

In place of the 60–40 tests, we proposed a more flexible standard that would still assure that referring sources, physicians in particular, were not inappropriately selected as investors. First, we proposed requiring the entity to make a *bona fide* offer of the investment interest to any individual or entity irrespective of whether such prospective investor is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. Thus, we proposed requiring that opportunities for investment be offered in a good faith, non-discriminatory manner to any individuals or entities that are potential sources of capital. Second, to exclude the possibility of sham business structures not intended to serve the rural areas in which they are located, we proposed incorporating a standard that would require that at least 85 percent of the dollar volume of the entity's business in the previous fiscal year or twelve month period be derived from items and services provided to persons residing in the rural area. For entities that have not been in business for 12 months, compliance with this standard would be determined by examining the composition of the entity's business over the entire period of its existence.

Methods of Classifying Geographic Areas: Depending on its purpose, the Government uses several methodologies to define whether certain geographic areas are ''urban'' or ''rural'' and whether certain geographic areas or populations have inadequate access to health care services. Among them, the following are relevant to this preamble discussion:

- *OMB Methodology:* The OMB defines a Metropolitan Statistical Area (MSA) as a group of counties (or, in New England, a group of townships) surrounding and related to an urban core area containing a large population nucleus. The core of an MSA is a city with a population of at least 50,000 people and/or an urbanized area with a total population of at least 100,000 (75,000 in New England). The OMB defines a county as part of the MSA if it contains the core city or contains part of a continuous urbanized area around the core city, even if outlying areas of the county are rural in character. Using this methodology, an area may be considered ''rural'' if it is not metropolitan, e.g., not part of an OMB-defined MSA (see 44 U.S.C. 3504).
- *HCFA DRG Definition:* For purposes of establishing DRG payments, HCFA defines ''rural'' areas as all areas outside the metropolitan areas (MSAs) defined by OMB (§ 412.62(f)(1)(ii)).
- *Medically Underserved Areas/Populations (MUA/MUPs):* The MUA/MUP system was developed in the 1970s in accordance with section 330(b)(3) of the Public Health Service (PHS) Act to identify areas and populations eligible to participate in the Community Health Center Program. MUAs and MUPs are designated by the Health Resources and Services Administration (HRSA). An MUA is either a rural or urban area designated by the Secretary as having a shortage of health care services; an MUP is a population group designated as having such a shortage, such as certain migrant farmworkers or homeless populations. Factors HRSA considers as part of the existing MUA/MUP designation process include population-to-primary care physician ratios, infant mortality rates, poverty rates, and the percentage of the population aged 65 or over. The regulations governing MUA/MUPs are currently set forth at 42 CFR part 51c.
- *Health Professional Shortage Areas (HPSAs):* HRSA developed HPSAs to meet the statutory requirement in section 332 of the PHS Act to designate areas, population groups and facilities with a shortage of health professionals eligible for placement of National Health Services Corps personnel. HPSA designations are currently based primarily on measurements of area population-to-provider ratios for specific geographic service areas (or population groups within those areas), together with indicators that provider resources in adjoining areas are overutilized, excessively distant (e.g., more than 30 minutes travel time away for primary care) or otherwise inaccessible (42 CFR part 5). A HPSA can be designated based on shortages of (1) providers in a geographic area; (2) providers willing to treat a specific population within a defined area; or (3) providers for a public or nonprofit facility serving a designated area or population group (which could include a hospital). HPSAs are identified for three types of provider shortages: primary care, dental care and mental health care. The current primary care HPSA criteria define a ''primary care physician'' as a physician in one of the following specialties: general practice, family practice, pediatrics, general internal medicine or obstetrics/gynecology. Mental health providers covered by mental health HPSA designations include psychiatrists, clinical psychologists, psychiatric nurses, psychiatric social workers and marriage counselors.
- *Notice of Proposed Rulemaking on MUA/MUPs and HPSAs.* HRSA has proposed revising the MUA/MUP and HPSA regulations to improve the current designation process by combining the two designation processes; automating the scoring process and simplifying it by maximizing the use of national data; expanding States' roles in identification of rational service areas for designation; and incorporating better measures or correlates of health status and lack of access, including measures of minorities and isolated rural areas (63 FR 46538). In response to public comments, HRSA has announced its intention to issue a second notice of proposed rulemaking following a period of evaluation of comments received, analysis of alternative approaches and impact testing (64 FR 28831). Following an additional public comment period, new regulations governing MUA/MUPs and

HPSAs are expected to be codified at 42 CFR part 5.

Summary of Final Rule: Paramount among OIG's concerns is that beneficiaries have adequate access to quality health care. We are aware that certain communities experience shortages of health care services that affect Federal program beneficiaries and others. This rule for investments in underserved areas is designed to balance the interests of those communities in facilitating the development of health care services with the anti-fraud interests that are the basis of the anti-kickback statute.

Health care joint ventures in underserved areas raise the same basic anti-kickback concerns as other joint ventures: First, is the joint venture a *bona fide* business enterprise? Second, are distributions from the joint venture really payments for referrals to the joint venture from investors? Third, are the distributions really payments for referrals from one investor to another? For this reason, it is important that any safe harbor contain adequate safeguards and conditions against fraud and abuse.

This new safe harbor for investments in joint ventures in underserved areas is designed to provide additional flexibility for investments in underserved areas that may experience a shortage of available capital from non-referral source investors. The safe harbor includes specific criteria that substantially reduce the risk of inappropriate payments for referrals and exclude from protection entities that do not serve the health care needs of people living in the underserved areas in which the entities are located. Because the safe harbor affords protection for a broader range of investments in joint ventures in underserved areas, we hope it will promote the development of needed health care ventures.

Based on our review of the comments received from, and concerns expressed by, various commenters, we have made several significant changes to the proposed safe harbor, all of which are described in more detail in the responses to comments section below.

- First, we have expanded safe harbor protection to include urban, as well as rural, underserved areas. We are persuaded that joint ventures in urban underserved areas often experience the same difficulties in qualifying for safe harbor protection as their rural counterparts. We are defining an underserved area as any defined geographic area that is designated as a MUA in accordance with the regulations at 42 CFR part 51c (or, if and when applicable, 42 CFR part 5).
- Second, we have reduced from 85 percent to 75 percent the volume of the investment entity's business that must be derived from residents of underserved areas.
- Third, we have provided a ''grace'' period for investment entities that qualify for safe harbor protection at the time of the initial investment, but subsequently find themselves located in areas that have ceased to meet the safe harbor definition of an underserved area.
- Fourth, we have incorporated a modified investor rule that requires that at least half of the investment interests in the entity be held by non-referral source investors. Here, we were in part persuaded by comments from health care entities that are currently located in underserved areas and that have no or few referral source investors. These entities expressed concern about unfair competition from new entities entirely composed of referral source investors (primarily physicians) in markets with few referral sources. We were also concerned about limiting inappropriate financial incentives.

Comments and Responses

Comment: We solicited comments regarding the appropriateness of our proposal to define ''rural'' with reference to the OMB standards for MSAs. In response, several commenters urged us to adopt our alternative proposal to use the rural definition employed by HCFA for purposes of reimbursing hospitals located in rural areas under DRG payment rates (42 CFR 412.62(f)(1)(iii)). A number of commenters urged us to extend the investment interest safe harbor for rural entities to equally qualified underserved urban areas.

Response: One of the important issues in designing this safe harbor is how to define geographically the scope of investments to which it applies. After consideration and examination of various approaches to defining ''rural'' for purposes of this safe harbor, we have decided to limit this safe harbor to investment interests in entities located in areas defined by HRSA as MUAs (that otherwise meet all safe harbor eligibility standards). This decision responds to requests for safe harbor protection to facilitate investment in areas demonstrably experiencing difficulty in attracting needed health care services. Unlike OMB's MSAs, which merely measure geographic distributions of population, MUAs identify areas experiencing health care shortages by accounting for such factors as poverty levels, infant mortality, and population age. Thus, we are amending the rule to substitute MUAs for the existing definition of ''rural'' to more closely tailor the safe harbor to protect investment interests in entities located in underserved areas.

In addition to more accurately targeting rural areas with shortages of health care services, protecting investments in MUAs offers a means of expanding safe harbor protection to urban underserved areas. We are persuaded that many urban underserved areas experience difficulties in attracting investments in health care services that are comparable to those experienced in rural areas. Because one of our objectives in creating this safe harbor is to foster the development of needed health care services, we believe it makes sense to protect qualified investments in defined shortage areas without regard to density of population.

At the time of publication of this rulemaking, HRSA's final regulations on the new process for designating MUAs are still pending. Although we anticipate that those regulations will be finalized, we are persuaded that, even in the absence of that rule, and notwithstanding certain concerns we have regarding the administration of the current program, our selection of MUAs as a basis for this safe harbor is sound and more consistent with the stated purpose of the safe harbor than either of our original proposals for identifying the covered areas.

We anticipate that, if finally promulgated, HRSA's new rule for evaluating and designating MUAs may result in some areas presently classified as MUAs losing their classifications. Moreover, HRSA has indicated its intent to review MUA classifications regularly, resulting in the possibility that some areas could periodically lose their classifications. Given this potential, it is incumbent on us to address the effect of the loss of a MUA designation on an entity protected by the safe harbor for investments in underserved areas. If an entity that meets all of the safe harbor standards were located in an area that loses its designation as a MUA after the entity has initially qualified for the safe harbor, the entity would technically no longer fit squarely within the safe harbor and would lose its protection. However, we are mindful of the need investors have for reasonable certainty in their arrangements and the significant effect a sudden loss of safe harbor protection resulting from circumstances outside their direct control may have on investors. Accordingly, we are including in this safe harbor a 3-year grace period during which such entities will be protected, provided they continue to meet all of the other safe harbor

conditions. This grace period will afford entities that wish to maintain safe harbor protection an opportunity to restructure so as to qualify for the small entity investment interest safe harbor at § 1001.952(a)(2). We wish to iterate that loss of safe harbor protection does not mean that a joint venture arrangement becomes unlawful.

Comment: Several commenters expressed concern about our proposal to eliminate the 60–40 tests of the small entity investment safe harbor for purposes of this safe harbor. One commenter advocated that the 60–40 rules should continue to apply to facilities located in rural areas to prevent a proliferation of unnecessary facilities, especially laboratories, that are dependent on referrals from investor-physicians. Another commenter supported restricting the safe harbor only to rural areas where alternative sources of a particular service are not otherwise available. These commenters argued that a proliferation of protected entities with large numbers of referral source investors could adversely affect existing entities in rural communities. One commenter suggested that we use a ''demonstrated community need'' standard instead of limiting safe harbor protection to defined geographic areas. This commenter further recommended that entities that meet such a ''demonstrated community need'' test be required to disclose to patients a referring physician's ownership interest and to conduct utilization review of an entity's services.

Response: Having considered these comments, we are persuaded that eliminating both 60–40 rules, and in particular the 60–40 investor rule, may lead to inappropriate financial incentives and unfair competition in some areas by allowing referral source investors, primarily physicians, to ''lock up'' the market for particular services in those areas. Ensuring fair competition in the health care marketplace is one of the goals of the anti-kickback statute. We are also concerned that an excessive proliferation of particular services in rural or urban underserved areas could lead to overutilization by entities competing for scarce revenue and could prompt protected entities to develop revenue streams from patients not residing in underserved areas, in contravention of the intent and spirit of the safe harbor.

MUA designations are not made on a service-specific basis; thus, an area may qualify as a MUA based on an overall shortage of health care services even if it has a sufficient supply of a particular heath care service. As we stated in the preamble to the 1993 proposed rule, one of the purposes of this safe harbor is to ensure adequate access to medical care for patients in underserved areas. Our intent was to design a safe harbor that would accomplish this purpose, while excluding ventures that do not serve the underserved areas in which they are located. We remain persuaded that there are many rural and urban underserved areas with legitimate shortages of health care services and limited sources of potential investors. However, while we believe that market competition should minimize the number of duplicative ventures in a particular underserved area, we are persuaded that safe harbor protection should be limited, to the extent practicable, to ventures that fill a genuine health care need of area residents.

In light of our intention to minimize safe harbor protection for redundant health care services owned by referral source investors in otherwise underserved areas, reduce inappropriate financial incentives, and maintain fair competition for providers that are not owned by referral source investors, we have revisited our original proposal to eliminate both of the 60–40 tests of the small entity investment safe harbor for purposes of this safe harbor. In this final rule, we are adopting our original proposal to eliminate the 60–40 revenue rule, but we are retaining a modified limitation on the number of interested investors. Specifically, we are requiring, as a condition for protection, that investors who make referrals or who are in a position to make referrals or furnish items or services to the entity not own more than 50 percent of the value of investment interests within each class of investments in the entity. As with the 60–40 investor rule in the small entity investment safe harbor, we are permitting equivalent classes of stock to be aggregated for purposes of determining safe harbor compliance.

We believe that eliminating the 60–40 revenue rule, thereby permitting entities to draw 100 percent of their revenue from referrals by investor-owners, should make investment in such entities sufficiently attractive to non-referral source investors so as to permit the entities to meet the new 50–50 investor test. We recognize that this safe harbor may not fully answer all of the concerns raised by the commenters and that there may be particular circumstances in which ventures with parties to existing health care entities can not qualify for safe harbor protection. Some of these ventures may be appropriate for protection through an advisory opinion (42 CFR part 1008). In addition, joint ventures in underserved areas may still qualify for protection under the small entity investment interest safe harbor at § 1001.951(a)(2).

We are not adopting the suggestion that we promulgate a ''demonstrated community need'' standard for this safe harbor. Such a standard would not create a sufficiently clear rule and would be unenforceable in practice. Moreover, the additional two standards suggested by one commenter—public disclosure of ownership interests and utilization review—while good practices, are not, in our experience, effective deterrents to fraud and abuse.

Comment: One commenter urged us to allow compliance with the rural investment safe harbor if an entity certified its inability to comply with the 60–40 rules in the small entity safe harbor despite its best efforts.

Response: A mere ''best efforts'' exception to the small entity investment interests safe harbor based on a certification from the investment entity would be insufficient to protect against abusive arrangements and would be impractical in application. Like all parties that cannot comply with a safe harbor, parties that are unable to comply with the 50–50 investor rule have recourse to the advisory opinion process for guidance about their specific arrangements.

Comment: One commenter requested that the OIG incorporate a ''fair market value'' principle more explicitly into the proposed rural investment safe harbor.

Response: The principle of ''fair market value'' is included in this investment safe harbor at § 1001.952(a)(3)(viii).

Comment: One commenter expressed concern that a rural referral center (RRC) that had been reclassified as located in an urban area by the Medicare Geographic Classification Review Board for purposes of Medicare payment (42 CFR 412.230) would not be eligible to receive protection under the rural investment interest safe harbor. RRCs are Medicare participating acute care hospitals that are located in rural areas and that qualify under HCFA rules as referral centers (see 42 CFR 412.96). Under certain circumstances, an individual hospital, including a referral center, may be redesignated from a rural area to an urban area for purposes of using the urban area's standardized amount for inpatient operating costs, wage index value, or both. (42 CFR 413.230).

Response: A RRC located in a MUA would be eligible for protection under the rural investment interest safe harbor, provided it meets all of the conditions of the safe harbor. Reclassification as

''urban'' for Medicare payment purposes would not bar safe harbor protection.

Comment: Several commenters asked us to further explain how facilities can comply with the requirement that an entity must offer equal and *bona fide* opportunities to acquire investment interests to individuals or entities irrespective of whether such prospective investors are in a position to make or influence referrals to, furnish item or services to, or otherwise generate business for the entity (§ 1001.952(a)(3)(i)). In the alternative, a commenter requested that this provision be deleted. One commenter expressed concern that the ''broad'' terms of the proposed safe harbor would make it difficult for parties to identify ''potential sources of capital'' and inquired whether satisfying the safe harbor required investment opportunities to be registered under Federal and State securities laws as public offerings. Another commenter expressed concern about publicizing investment opportunities in rural areas where investors often do not wish to be publicly identified.

Response: Our intent in proposing the ''equal and *bona fide* opportunities'' standard was to ensure that investment opportunities are offered in a good faith, nondiscriminatory manner to any individuals or entities that are potential sources of capital, so that referral source investors are not inappropriately selected as investors. In light of our decision to require that at least 50 percent of the investment interests be held by non-referral source investors, we have concluded that this standard is not necessary. Accordingly, we are not adopting it in the final rule.

Comment: The sixth standard of the proposed safe harbor required that at least 85 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period be derived from services provided to persons residing in the underserved area. One commenter asked us to lower the 85 percent dollar volume requirement to 40 percent in order to make the threshold more attainable and allow more investment interests to qualify for protection.

Response: As we explained in the preamble to the 1993 proposed rule, although we proposed eliminating the 60–40 revenue rule for investments for purposes of the proposed safe harbor, we remained concerned that a sham joint venture structure could be established that does not intend to serve the underserved area in which it is located. This safe harbor responds to requests for assistance in facilitating investment in underserved areas. It is not unreasonable to offer this safe harbor protection only to investments in entities that will primarily serve underserved populations by providing services needed in their communities. We are persuaded, however, that lowering the required percentage to 75 percent would adequately protect against abuses and further the purpose of this safe harbor. Accordingly, we are requiring that at least 75 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period be derived from services provided to persons residing in an underserved area or persons who are members of a MUP (as defined by HRSA).

2. Ambulatory Surgical Centers

Summary of Proposed Rule: We proposed a fourth investment interest safe harbor to protect payments to investors in ambulatory surgical centers (ASCs) who are surgeons who refer patients directly to the ASC and perform surgery themselves on these referred patients. What we intended to protect is often understood conceptually as an extension of the physician's office space. We further explained that a safe harbor for investment interests in ASCs was warranted because the professional fee generated by a referral from a physician-investor to the ASC is substantially greater than the facility fee generated by the referral, and therefore profit distributions to physician-investors, which are derived from the facility fee, do not constitute a significant improper inducement to make referrals. The rationale underlying the proposed safe harbor would not extend to investment interests held by physicians who are not in a position to refer patients directly to the ASC and perform surgery. We explained that the concern with investments by such physicians is the potential for indirect kickbacks, because they might receive a return, through the ASC's profit distribution, for referrals of patients to other investors who perform surgical procedures at the ASC. We solicited comments on whether the rationale underlying this safe harbor is applicable to entities other than ASCs. We also specifically solicited comments on what degree of disparity should exist between the professional fee and the facility fee generated by referrals to a type of entity for that type of entity to receive safe harbor protection.

The proposed safe harbor applied only to ASCs certified under 42 CFR part 416. We did not propose protecting ASCs located on the premises of a hospital that share operating or recovery room space with the hospital for treatment of the hospital's inpatients or outpatients. The proposed safe harbor contained the following 5 standards:

- The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished or the amount of business otherwise generated from that investor to the entity.
- There is no requirement that a passive investor, if any, make referrals to the entity as a condition for remaining an investor.
- Neither the entity nor any investor may loan funds to, or guarantee a loan for, an investor if the investor uses any part of such loan to obtain the investment interest.
- The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.
- Each investor must agree to treat patients receiving Medicare or Medicaid benefits.

In contrast to the other investment interest safe harbors that limit investment by individuals in a position to refer, the proposed ASC safe harbor would have only protected entities whose investment interests were held *entirely* by such individuals. With that distinction in mind, four of the five standards were adapted from the standards in the small entity safe harbor (§ 1001.952(a)(2)). We solicited comments on the extent to which other standards were appropriate to safeguard against potential abuse.

Summary of Final Rule: The OIG received nearly two hundred comments relating to the proposed safe harbor for investment interests in ASCs. As a result of these comments, we have significantly reworked this safe harbor to provide, in general, expanded safe harbor protection for investments in ASCs.

As an initial matter, our proposed placement of the ASC safe harbor with the investment interests safe harbor appears to have caused confusion as to the safe harbor's purpose and scope. Our proposed ASC safe harbor contemplated a joint venture composed entirely of referral source investors. Placing these regulations alongside the large entity safe harbor, which limits safe harbor protection to investments that are so small as to be, at most, tangentially related to referrals, and the small entity investment safe harbor, which limits safe harbor protection to ventures composed of no more than 40 percent referral source investors, led

some commenters to question why an ASC with 100 percent referral source investors would pose less risk of fraud and abuse than another type of investment entity with a smaller percentage of referral source investors. The answer is that ASC investments do not necessarily pose less risk. Rather, as described in more detail below, investments in ASCs raise concerns that are different from those addressed by the small entity investment safe harbor; therefore, investments in ASCs warrant different safe harbor criteria, including different safeguards, limitations and controls.

The new ASC safe harbor has four categories: Surgeon-Owned ASCs, Single-Specialty ASCs, Multi-Specialty ASCs, and Hospital/Physician ASCs. Safe harbor protection requires full compliance with all of the standards of any one category. All four categories have the following requirements in common: (i) The ASC must be certified under 42 CFR part 416; (ii) loans from the entity or other investors for the purpose of investing are prohibited; (iii) investment interests must be offered on terms not related to the volume or value of referrals; (iv) all ancillary services must be directly and integrally related to primary procedures performed at the ASC and none may be separately billed to Medicare or other Federal health care programs; and (v) neither the ASC nor physicians practicing at the ASC can discriminate against Federal health care program beneficiaries. Additional specific standards apply to particular categories. Moreover, in the interest of ensuring patient freedom of choice and promoting informed decision-making by patients, we have included a requirement in each category that patients referred to the ASC by an investor be fully informed of the investor's investment interest.

The four categories are summarized here and described in greater detail in the responses to comments below:

- *Surgeon-Owned ASCs.* The first category is designed to protect ASC investments where all of the physician investors are either general surgeons or surgeons engaged in the same surgical specialty. Specifically, category one protects certain investments in entities where all of the investors are either (i) general surgeons or surgeons engaged in the same surgical specialty, all of whom are in a position to refer patients directly to the ASC and perform procedures on such referred patients; (ii) group practices that are composed of such surgeons and that meet all of the requirements of the group practice safe harbor (§ 1001.952(p)); or (iii) investors who (a) do not provide items or services to the ASC or its investors, (b) are not employed by the ASC or any investor, and (c) are not in a position to refer patients directly or indirectly to, or generate business for, the ASC or any of its investors. A surgeon is considered to be in a position to refer patients directly and perform procedures if he or she derives at least one-third of his or her medical practice income from all sources for the previous fiscal year or previous 12-month period from his or her own performance of procedures that require an ASC or hospital surgical setting in accordance with Medicare reimbursement rules (the ''one-third practice income'' test).
- *Single-Specialty ASCs.* The second category is similar to the first category, except that it is designed to protect ASC investments where all of the physician investors are engaged in the same medical practice specialty (*e.g.*, gastroenterologists), provided that they perform ASC procedures as a significant part of their medical practices. The physicians that qualify under this category need not be traditional surgeons. Specifically, category two protects certain investments in entities where all of the investors are either (i) physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the ASC and perform procedures on such referred patients; (ii) group practices that are composed of such physicians and that meet all of the requirements of the group practice safe harbor (§ 1001.952(p)); or (iii) investors who (a) do not provide items or services to the ASC or its investors, (b) are not employed by the ASC or any investor, and (c) are not in a position to refer patients directly or indirectly to, or generate business for, the ASC or any of its investors. As with category one (Surgeon-Owned ASCs), physician investors must meet the ''one-third practice income'' test.
- *Multi-Specialty ASCs.* The third category is similar to the first two categories, but it allows a mix of the types of physicians addressed in those categories. Thus, the third category protects certain investments in entities where all of the investors are either (i) physicians (surgeons or non-surgeons) who are in a position to refer patients directly to the ASC and perform procedures on such referred patients; (ii) group practices that are composed of such physicians and that meet all of the requirements of the group practice safe harbor (§ 1001.952(p)); or (iii) investors who (a) do not provide items or services to the ASC or its investors, (b) are not employed by the ASC or any investor, and (c) are not in a position to refer patients directly or indirectly to, or generate business for, the ASC or any of its investors. The physicians must meet the ''one-third practice income'' test described in the preceding paragraphs. In addition, physicians in this category must meet a second standard related to practice income because of the increased risk of remuneration for referrals among physicians with different specialties. Specifically, the rule requires that at least one-third of the physician's procedures that require an ASC or hospital surgical setting (in accordance with Medicare reimbursement rules) be performed at the ASC in which he or she is investing. We believe that for physicians who meet the ''one-third/one-third'' test, an investment in an ASC truly qualifies as an extension of the physician's office. We believe such physician investors are unlikely to have significant incentives to generate referrals for other investors because of the minimal additional return on investment derived from such referrals.
- *Hospital/Physician ASCs.* The fourth category protects certain investments by hospitals in ASCs. To qualify for the safe harbor, at least one investor must be a hospital and the other investors must be (i) physicians or group practices that otherwise qualify under the safe harbor or (ii) non-referral source investors. The hospital must not be in a position to refer patients directly or indirectly to the ASC or any physician investor. The ASC space must be dedicated exclusively to the ASC and not used by the hospital for the treatment of the hospital's inpatients or outpatients. The ASC may lease space that is located in or owned by a hospital investor, if the space lease qualifies for protection under the space rental safe harbor. Equipment and personal services provided by the hospital must similarly meet safe harbor requirements.

In this final rule, we are expressly departing from the underlying rationale for our original safe harbor proposal, which was the professional fee/facility fee differential. The existence of a significant disparity between the facility fee and the professional fee, such that the facility fee is significantly smaller than the professional fee, minimizes the risk of improper incentives for referrals; however, we are aware that professional and facility fees have changed and may continue to change over time and that the ratio between them will not always, by itself, provide a clear basis for safe harbor protection. So although the fee differential was meaningful at the time, we will in the future look more broadly for indicia that an ASC investment represents the extension of a physician's

office space and not a means to profit from referrals.

The gravamen of an anti-kickback offense is payment of remuneration to induce the referral of Federal health care program business. In the context of an ASC, our chief concern is that a return on an investment in an ASC might be a disguised payment for referrals. Two examples illustrate the potential problem. First, primary care physicians could be offered an investment interest in an ASC for a nominal capital contribution as an incentive to refer patients to surgeon owners of the ASC. The primary care physicians would not perform any services at the ASC, but would profit from any referrals they make. Second, physicians in specialties that typically refer to one another could jointly invest in an ASC so that they are positioned to earn a profit from such referrals or so that one physician specialty provides the ASC services and the other provides the referrals. In such cases, medical decision-making may be corrupted by financial incentives offered to potential referral sources who stand to profit from services provided by another physician.

With the above concern in mind, we are still able to provide safe harbor protection for certain non-surgeon physicians, group practices and hospitals that meet certain requirements set forth in the safe harbor. These requirements are designed to preclude protection for investors who might have incentives to generate returns on their investments through referrals to other investors or to other physicians who perform procedures at the ASC. The safe harbor will also protect some investment interests held by persons who are not in a position to make or influence referrals either directly or indirectly to the ASC or to any of its investors.

However, except as otherwise described in the regulations, we are not protecting investment interests held by any party that provides items or services to, is in a position to influence the flow of referrals directly or indirectly to, or generates business for, the entity or any investor. Notwithstanding, investments by these parties are not necessarily unlawful, provided that payments made in return for the investment are not for the purpose of inducing or rewarding referrals.

Indeed, we recognize that some legitimate ASC arrangements may not fit precisely in the final ASC safe harbor. Those that do not fit may be eligible for safe harbor protection under the small entity investments safe harbor (§ 1001.952(a)(2)) or the new safe harbor for investments in underserved areas (§ 1001.952(a)(3)). Alternatively, current or potential investors may request an OIG advisory opinion in accordance with section 1128D(b) of the Act and the regulations at 42 CFR part 1008.

Our responses to public comments are summarized below.

Comments and Responses

Comment: Many commenters commended the OIG for proposing a safe harbor to shield ASCs from prosecution under the anti-kickback statute. Many commenters noted that ASCs have saved Medicare hundreds of millions of dollars, forcing hospitals to become more competitive, because ASC payment rates are typically lower than hospital payment rates for the same procedures. Several commenters stated that ASCs foster patient access to care, particularly in medically underserved regions. Moreover, many commenters observed that patients generally prefer outpatient surgical care at an ASC to hospital care.

Response: We agree that ASCs can significantly reduce costs for Federal health care programs, while simultaneously benefitting patients. The HCFA has promoted the use of ASCs as cost-effective alternatives to higher cost settings, such as hospital inpatient surgery. Where the ASC is functionally an extension of a physician's office, so that the physician personally performs services at the ASC on his or her own patients as a substantial part of his or her medical practice, we believe that the ASC serves a *bona fide* business purpose and that the risk of improper payments for referrals is relatively low. Where the criteria set forth in the safe harbor are satisfied, we do not consider investments in ASCs to be a likely source of overutilization of services payable by the Federal health care programs or increased program costs. We are concerned, however, that patient freedom of choice be protected and informed decision-making promoted in situations where a physician is required to refer to an entity that he or she owns in order to qualify for safe harbor protection. Accordingly, we are adding a requirement that the existence of the ownership interest be disclosed to patients. We note that such disclosure in and of itself does not provide sufficient assurance against fraud and abuse of the Federal health care programs. This conclusion derives from our observation that a disclosure of financial interest is often part of a testimonial, i.e., a reason why the patient should patronize that facility. Thus, often patients are not put on guard against the potential conflict of interest, *i.e.*, the possible effect of financial considerations on the physician's medical judgment.

Comment: Many commenters questioned our proposal to limit safe harbor protection to physicians who are ''surgeons'', given that many procedures or services performed in ASCs are performed by physicians not commonly called surgeons (*i.e.*, cardiologists, gastroenterologists, radiologists or pathologists). Many commenters argued that the ''extension of practice?'' rationale would apply to surgeons and such other physicians alike.

A number of commenters proposed that we adopt a definition of ''surgeon'' that would include any physician who performs procedures classified as surgical by HCFA regulations. For example, many kinds of endoscopy are classified as surgical procedures in accordance with 42 CFR 416.65 and various updates to the list of HCFA-approved ASC surgical procedures published in the **Federal Register** (see 42 CFR 416.65(c); 63 FR 32290 (1998) (to be codified at 42 CFR parts 416 and 488)). One commenter suggested that physicians who refer to an ASC, but do not perform services at the ASC, should be permitted in the safe harbor as long as they meet the safe harbor's five enumerated requirements.

Response: As discussed above, we agree that limiting the safe harbor to investors who are physicians traditionally termed ''surgeons'' is unnecessarily restrictive, especially in light of advancing technology and the scope of HCFA's approved list of ASC procedures. In light of the many comments received on this topic, we have revised the safe harbor to protect investments in ASCs certified under 42 CFR part 416 by non-surgeon physicians, group practices, hospitals and non-referral source investors that meet certain conditions. Investments by group practices and hospitals are discussed in responses to separate comments below.

With respect to physicians, we are promulgating three categories of safe harbor criteria, each designed to protect different types of physician investment. All of the categories protect combinations of qualifying physicians, which generally are those physicians who perform a substantial number of procedures listed on the HCFA ASC surgical procedures list as part of their medical practices. Specifically, at least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures that require an ASC or hospital surgical setting. In

addition, where there is a risk of referrals among physicians or surgeons in different specialties, we are requiring that each perform at least one third of his or her procedures that require an ASC or hospital surgical setting at the investment ASC. We believe these standards ensure that a physicians investment in an ASC will truly represent an extension of his or her office. Where physicians own an ASC in which they will personally perform a significant number of procedures, obvious and legitimate business and professional reasons exist for the ownership, including convenience, professional autonomy, accountability and quality control. Moreover, any risk of overutilization or unnecessary surgery is already present by reason of the opportunity for a surgeon to generate his professional fee; the additional financial return from the ASC is not likely to increase the risk of overutilization of procedures significantly. We believe that the ''one-third/one-third'' standards in the safe harbor ensure that physician investors will have no significant incentive beyond receipt of their professional fees to refer to the entity or any of its investors, because any return on investment will be attributable primarily to legitimate business and only tangentially to possible referrals of ASC business.

Because of the risk of remuneration for referrals, investments by other physicians, such as anesthesiologists, radiologists and pathologists, or by non-physician providers, such as certified registered nurse anesthetists, are not protected by the safe harbor if the physician or provider is in a position to provide items or services to, refer patients directly or indirectly to, or generate business for, the ASC or any of its investors. The determination whether an investor should be classified as a potential referral source is a factual question. As is the case for investments in small entities (56 FR 35964), we will accept a written stipulation that for the life of the investment the investor will not make referrals to, furnish items or services to, or otherwise generate business for, the entity or any of its investors, provided that, in fact, the investor's actions comport with the written stipulation. We wish to make clear that investments by these physicians and other providers do not necessarily implicate the anti-kickback statute. Finally, we note that we do not consider an investment by a physician's own wholly-owned professional corporation to be an excluded non-physician investment.

Comment: Many commenters also objected to our proposal to protect only ASCs owned entirely by surgeons who practice there. These commenters asserted that non-surgeons, and more specifically non-physicians, should be allowed safe harbor protection for investments in ASCs. Many commenters advocated a rule that would allow surgeon investors to transfer ownership to family members and other non-surgeons upon retirement or death without jeopardizing the ASC's safe harbor protection. Commenters also expressed concern that the safe harbor did not protect investments held by administrative staff at the ASC. Many commenters asserted that co-ownership with administrative staff would enable these individuals to make long-term commitments to providing better services in a cost-effective manner. Many commenters further expressed the view that anyone who is not in a position to refer patients to the ASC, including corporate entities such as for-profit management companies, should be eligible to invest in the ASC. Some commenters urged that investments held by a physician's retirement plan be protected.

Response: We are extending safe harbor protection to investors who are not in a position to provide items or services to the ASC or any of its investors and who are not in a position directly or indirectly to generate referrals for the entity or any of its investors. There is minimal risk that a payment made to such a non-referral source investor would implicate the anti-kickback statute, and accordingly investments by such investors do not taint the ASC investment. However, we believe that hospitals, skilled nursing facilities, home health agencies, managed care companies, physician practice management companies, and similar entities may be referral sources in some circumstances. By way of example only, a hospital may be in a position to influence referrals when it employs physicians who make referrals, when it owns surgical practices, or when it is affiliated with a ''friendly'' or ''captive'' professional corporation owned or controlled by its employees. We further believe that some employees, such as certain marketing and administrative staff, may be referral sources.

Comment: Many commenters argued that the scope of the safe harbor should be expanded to include facilities that are not traditionally considered ''surgical'' centers, such as lithotripsy facilities, end-stage renal disease (ESRD) facilities, comprehensive outpatient rehabilitation facilities (CORFs), radiation oncology facilities, cardiac catheterization centers and optical dispensing facilities. Many commenters argued that such facilities, like ASCs, are part of the physician's practice and are not simply vehicles for passive investment and self-referral. A number of commenters stated that such facilities would not encourage overutilization, would increase access to care, would reduce costs, and would maintain or improve quality of care. Several commenters averred that investments in such facilities offer little inducement because each investor makes very little profit from investments in such facilities, in part because in some facilities, each physician's investment is a small percentage of the whole. Other commenters stated that the cost of operating these facilities is so high that each investor's net revenues from the facility investment is marginal. Many commenters argued that existing regulation by Federal and State agencies and by physician associations creates sufficient checks on fraud and abuse.

Response: Our regulatory treatment of ASCs recognizes the Department's historical policy of promoting greater utilization of ASCs because of the substantial cost savings to Federal health care programs when procedures are performed in ASCs rather than in more costly hospital inpatient or outpatient facilities. Physician investment in ASCs was an important corollary to the Department's efforts to promote ASCs because physicians were natural sources of capital, since many hospitals were reluctant to open or invest in ASCs that competed with their own outpatient and inpatient surgery departments. Accordingly, many of the early ASCs were financed and owned by surgeons and other physicians who worked in them. Currently, HCFA's goal is to set payment rates that are consistent across different sites of service.[4] However, currently surgeries in ASCs generally continue to be reimbursed at lower rates.

Safe harbor protection for ASCs derives in large measure from this longstanding policy encouraging freestanding ASCs as a less costly alternative to hospitals for appropriate surgeries. In addition, Medicare's uniform, prospectively-established ASC payment methodology and the safe harbor's restriction on billing Medicare separately for ancillary services provide further assurance against abuse.

[4] *See e.g.*, Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998, 63 FR 32290, 32307 (to be codified at 42 CFR parts 416 and 488) (proposed June 12, 1998).

Investments by referring physicians or combinations of referring physicians and hospitals in non-ASC clinical joint ventures, including, but not limited to, cardiac catheterization laboratories, radiation oncology centers or ESRD facilities, do not share the same policy background and are not subject to the same reimbursement structure as investments by physicians in ASCs. Such clinical joint ventures may raise concerns not present with ASCs. In short, to qualify under this safe harbor, a facility must be a certified ASC under 42 CFR part 416. The existing small entity investment safe harbor (§ 1001.952(a)(2)) may be applicable for other joint ventures (assuming all safe harbor conditions are satisfied). In addition, we are not prepared at this time to extend safe harbor protection to non-HCFA-certified ASCs. Industry-promulgated standards, while welcome and often helpful in combating fraud and abuse, may not be sufficient to safeguard the Federal health care programs.

Comment: Several commenters asserted that hospitals with investment interests in ASCs should also be protected under the proposed ASC safe harbor. One commenter expressed the view that hospitals have no financial incentive to refer outpatient surgeries to ASCs because ASC net collections would be significantly lower than hospital net collections for the same procedures. By contrast, several other commenters suggested that hospitals would refer outpatient procedures to ASCs to enable the hospitals to focus resources on inpatient operations and treatments and the development of integrated delivery systems. Several commenters asserted that a hospital referral of a patient to an ASC would be an extension of the hospital's practice analogous to a surgeon's referral of a patient to an ASC. A number of commenters asserted that patients would benefit from using an ASC in close proximity to a hospital, and that creating an ASC would make efficient use of surplus hospital space.

Response: After reviewing the comments, we are persuaded that safe harbor protection should be extended to ASCs jointly owned by hospitals and physicians who qualify under the terms of this safe harbor. Although joint ventures between hospitals and physicians are often susceptible to fraud and abuse, precluding all safe harbor protection for hospital investors in ASCs may unnecessarily place hospitals at a competitive disadvantage if they are forced to compete with ASCs owned by physicians, who principally control referrals.

To be protected by the safe harbor, a hospital investment must meet all of the conditions set forth in the safe harbor. The hospital must not be in a position to make or influence referrals directly or indirectly to the ASC or to any of its physician investors. Whether this condition is met will depend on the facts and circumstances of particular arrangements. Any space used by the ASC that is located in, or owned by, the hospital must be leased in accordance with a lease arrangement that satisfies all of the criteria of the space rental safe harbor (§ 1001.952(b)). Similarly, any hospital equipment used by the ASC must be leased under an arrangement that satisfies the equipment rental safe harbor (§ 1001.952(c)), and any personal services provided by the hospital must be provided in accordance with a contract that complies with the personal services and management contracts safe harbor (§ 1001.952(d)). To further mitigate the risk of improper cost-shifting, in no event may operating or recovery room space be shared with the hospital for the treatment of the hospital's inpatients or outpatients, nor may the hospital reflect or include any costs associated with developing or operating the ASC on any Federal health care program claim or cost report (except such non-reimbursable costs as may be required by the programs).

Comment: Many commenters expressed the view that a safe harbor that protects an investment where 100 percent of the investors are physicians would be inconsistent with the 60–40 investor rule in the existing investment interest in small entities safe harbor. Several commenters argued that imposing a new 100 percent rule would be burdensome on those investors who diligently tried to comply with the 40 percent rule.

Response: We are not changing the rules for those ASCs that meet the criteria for the ''small entity'' safe harbor. However, many existing ASCs that are owned entirely or predominantly by the physicians who practice there cannot fit within the ''small entity'' safe harbor and thus are not currently afforded safe harbor protection. Depending on the circumstances, either this new safe harbor, the ''small entity'' safe harbor (§ 1001.952(a)(2)), or the new ''underserved areas'' safe harbor (§ 1001.952(a)(3)) may offer protection to investors in an ASC.

Comment: Several commenters requested clarification of the requirement that a participating practitioner ''must agree to treat'' Medicare and Medicaid patients. Some commenters noted that it was unclear what level of participation in these Federal health care programs would satisfy the requirement. One commenter questioned whether the safe harbor would require treating Medicare and Medicaid patients to the exclusion of other patients if capacity were limited. Two commenters questioned whether it was sufficient to ''agree to treat'' instead of actually treating Medicare and Medicaid patients. Another commenter wondered whether all investors in the facility must treat Medicare and Medicaid patients. One commenter suggested that the requirement be deleted from the safe harbor. Another suggested that each ASC maintain records, on an annual basis, to show that it actually provided services to Medicare and Medicaid patients in proportion to those patients in the community. Several commenters noted that the requirement to treat Medicare and Medicaid patients is unnecessary because the anti-kickback statute is implicated only when Federal health care program reimbursement is requested.

Response: The requirement that all protected investors agree to treat Medicare and Medicaid patients is intended to ensure Medicare and Medicaid patients access to care at ASCs on a non-discriminatory basis. Thus, decisions whether to accept and treat Federal health care program beneficiaries must be made on a nondiscriminatory basis. This requirement is further intended to promote cost savings for the programs by encouraging investors to provide services for Federal program beneficiaries in ASCs rather than hospitals in medically appropriate circumstances. We do not intend to exclude from protection physicians who are not accepting any new patients. We are not adopting the suggestion that ASCs demonstrate that they provide services to Medicare and Medicaid patients in proportion to the numbers of those patients in the community. We find that requirement to be too limiting. We are clarifying the language of the safe harbor to make clear its anti-discrimination purpose, and we are expanding it to require non-discriminatory treatment of all Federal health care program beneficiaries.

The commenter is correct that the anti-kickback statute would not be implicated, and no safe harbor protection required, if the investor physicians were not in a position to make referrals of or otherwise generate business payable in whole or in part under a Federal health care program. However, given the number of Federal health care programs, which include

Medicare, Medicaid, TRICARE, Veterans' Administration, Public Health Service, Indian Health Service, and children's health insurance under Title XXI of the Act, we think it likely that most investor physicians will potentially be in a position to refer Federal program business.

Comment: One commenter was concerned that States might interpret State self-referral prohibitions as also prohibiting surgeons in ASCs from referring patients to the ASC for related laboratory, radiology and other ancillary services, and asked that we clarify that, under this safe harbor, such ''self-referrals'' would be permissible.

Response: We are not in a position to comment on State self-referral prohibitions. The ASC safe harbor is not intended to protect payments derived from ancillary services performed at or by the ASC, unless such services are directly and integrally related to the primary procedure performed at the ASC. Thus, for example, payments in connection with invasive radiology (a procedure in which an imaging modality is used to guide a needle, probe, or catheter accurately) would be protected, while payments for diagnostic or therapeutic radiology would not be protected. To clarify the safe harbor on this point, we have added a requirement that all ancillary services for Federal health care program beneficiaries performed at or by the ASC be directly and integrally related to primary procedures performed at the ASC and that no ancillary services be separately billed to the programs. Simply stated, because of the risk of overutilization of ancillary services, this safe harbor does not protect ancillary services joint ventures married to ASCs. Payments to providers of ancillary services may be protected under the employee compensation or personal services contract safe harbors, if the arrangements meet all applicable criteria.

Comment: A number of commenters expressed the opinion that integrated multispecialty or single-specialty group practices, as well as HMOs, should be able to develop ASCs as part of the practice network or HMO. With respect to HMO ownership and operation of ASCs, one commenter requested that the safe harbor permit such ownership even if physicians own the HMO and would be referral sources for the ASC.

Response: We have revised the safe harbor to protect explicitly group practice investments in qualifying ASCs. To be protected, a group practice investor must meet the requirements for the group practices safe harbor at § 1001.952(p) and be composed entirely of physicians who meet all of the criteria for protection as individual investors under the ASC safe harbor. Nothing in these regulations is intended to preclude the development of ASCs by HMOs, provided such arrangements do not include impermissible payments of remuneration to induce or reward referrals of Federal program business. These rules merely describe a certain subset of lawful practices that are deemed protected from prosecution under the anti-kickback statute.

Comment: At least one commenter suggested that the safe harbor be expanded for ASCs in rural areas, so that any individual or entity who is financially able to invest may do so, on the ground that there is a great need for ASCs and limited ability to capitalize them in rural areas.

Response: We believe that the provisions of this safe harbor will permit most investors who are in a position to capitalize ASCs in rural areas to do so. No special exception is necessary. Investors in an ASC located in a rural area may qualify for safe harbor protection under the investment interests in ASCs safe harbor, the investment interests in small entities safe harbor, or the new investment interests in underserved areas safe harbor. Investors in ASCs need only satisfy one safe harbor to qualify returns on their investments for protection from prosecution under the anti-kickback statute.

3. Investment Interests In Group Practices

Summary of Proposed Rule: We proposed a new safe harbor to protect payments to investors in entities composed only of active investors in a group practice. This safe harbor would have protected the investment interests of members of group practices that met certain prerequisites and standards. We proposed adopting the definition of group practice contained in the Stark Law at section 1877(h)(4) of the Act. The Stark Law prohibits Medicare payment where physicians make referrals for designated health services to entities in which they have an ownership interest or with which they have a compensation arrangement, unless that interest or arrangement meets the strict terms of a statutory exception. In the proposed safe harbor, we intended principally to protect investors who are individuals who qualify as ''physicians'' under the Stark Law definition; however, our definition of group practice permitted a physician to invest as a professional corporation, if the corporation were exclusively owned by the physician. The proposed safe harbor was intended to protect any payment that is a return on an investment interest (such as a dividend or interest income) made to a physician member of a group practice who is an ''active investor'' in the investment entity, as long as all of the standards in the safe harbor were satisfied. For example, the safe harbor would have protected any payments resulting from the ownership of an interest in the group practice itself. It also could have been read—although it was not intended—to protect dividends from an investment in an MRI facility to which the physician-investors referred patients, if the investment met the terms of the safe harbor. The proposed safe harbor was not intended to protect other payments made by group practices, such as salary payments to employees of a group practice or payments to independent contractors.

We solicited comments on the appropriateness of our definition of group practice. We further solicited comments on the appropriateness of incorporating standards from the second investment interest safe harbor (§ 1001.952(a)(2)), including the prohibition on preferential terms of an investment interest being offered to certain physicians based on expected referrals; the prohibition on loans or loan guarantees from the entity or another investor used to obtain the investment interest; and the requirement that the amount of the return on an investor's investment must be directly proportional to the capital invested. In particular, we solicited information regarding the types of compensation arrangements that exist within group practices and the extent to which such compensation arrangements create inappropriate incentives that might distort the professional judgement of the members of the group. Lastly, we solicited comments on how we might expand the proposed safe harbor to other types of joint ventures composed exclusively of active investors.

We received over a dozen comments on this proposal. While some commenters supported the safe harbor and some opposed it, most questioned the need for the safe harbor and indicated that it would cause confusion among existing group practices. Moreover, it became apparent from reviewing the comments that the intended scope of the safe harbor was not clear. Some commenters understood the safe harbor to protect investments in group practices; others believed it protected investments by group practice members in other entities. A few commenters believed it covered both types of investments.

Summary of Final Rule: Because of the evident confusion caused by the proposed safe harbor, and for reasons more fully explained below, we have decided not to promulgate the safe harbor in the form it was originally proposed. Instead, we are adopting a simpler, although perhaps narrower, safe harbor that protects returns on investments in the group practice itself (i.e., not in separately owned health care services), if the group practice meets the Stark Law definition of a group practice (section 1877(h)(4) of the Act) and if the group practice investors are all licensed professionals who practice in the group. The safe harbor also protects investments in solo practices where the practice is conducted through the solo practitioner's professional corporation or other separate legal entity. The anti-kickback statute is not otherwise implicated for investments by solo practitioners in their practices. The safe harbor protects returns derived from in-office ancillary services that qualify for the exception for ''in-office ancillary services'' under the Stark Law (section 1877(b)(2) of the Act). This safe harbor does not protect investments made jointly by group members in separate entities. The general parameters of this new safe harbor were suggested in comments submitted by a group practice trade association as a less complicated alternative to our proposed safe harbor language.

Specifically, the new safe harbor imposes four criteria. First, the equity interests in the practice or group must be held by licensed professionals who practice in the practice or group. The equity interests may be held by an individual professional corporation if the corporation is exclusively owned by a single individual. Second, the equity interests must be in the practice or group itself, and not some subdivision of the practice or group. Third, the practice (unless a solo practice) must meet the definition of ''group practice'' in section 1877(h)(4) of the Act and implementing regulations. Fourth, profit distributions derived from in-office ancillary services are only protected if the services meet the definition of ''in-office ancillary services'' in section 1877(b)(2) of the Act and implementing regulations. We believe these conditions will offer reasonably broad safe harbor coverage for integrated medical practices, while at the same time minimizing financial incentives that could lead to inappropriate utilization and increased program costs.

Conceptually, this new safe harbor is consistent with the accommodation for referrals between group practice members contained in the safe harbor for specialty referral arrangements (§ 1001.952(s)). In our preamble to the 1993 proposed rule, we explained that revenues shared between members of a group practice as a result of a referral from one member of the group to another are an inherent part of belonging to a group practice. This safe harbor protects such payments, provided all safe harbor conditions are satisfied.

We want to emphasize our view that under section 1877(h)(4) of the Act, a group practice must consist of one legal entity and must be a unified business with centralized decision-making, pooling of expenses and revenues, and a distribution system that is not based on satellite offices operating as if they were separate enterprises or profit centers. This safe harbor is not intended to protect group practices that are not legally organized, but instead only hold themselves out as groups. Nor is this safe harbor intended to protect multiple groups of physicians that remain in many ways separate, but join together for selective purposes, such as taking advantage of the exceptions in section 1877 of the Act that apply to group practices. For purposes of these regulations, a group practice may be one legal entity if it is composed of owners who are individual professional corporations or is owned by physicians who are individually incorporated.

Comments and Responses

Comment: One commenter supported a safe harbor based on the definition of ''group practice'' contained in section 1877(h)(4) of the Act, but objected to the application of any other standards or conditions. This commenter argued that a *bona fide* group practice can be equated, for fraud and abuse purposes, with sole-practitioner medical practices in that any remuneration shared or exchanged among the members of the group and any investment made jointly by the group in an entity to which the members of the group practice may make referrals and which can be considered as ''extension'' of the group practice should be regarded as a self-referral. On the other hand, some commenters expressed concern regarding the anti-competitive effects of protecting group practice investments in ancillary services and the attendant increased risk of abusive practices, including overutilization. Commenters suggested that the safe harbor include a requirement for public notice of group practice investment in ancillary services entities and notices to patients identifying alternative service providers.

Response: We agree that, generally speaking, safe harbor protection is warranted for remuneration shared or exchanged among the members of a group practice that meets the definition of a group practice under the Stark Law (section 1877(h)(4) of the Act). However, we are persuaded that investments by group practice members in entities that provide ancillary services may have anti-competitive effects and may result in abusive arrangements and incentives to overutilize those ancillary services. Accordingly, we do not believe that safe harbor protection is warranted for group practice investments in ancillary services at this time. Of course, investments in ancillary services may be covered by the small entity investment safe harbor. This new safe harbor for investments in group practices protects remuneration derived from in-office ancillary services, as defined in section 1877(b)(2) of the Act and implementing regulations.

Comment: Some commenters questioned the need to protect physicians' investments in their own group practice, and suggested that the anti-kickback statute is not implicated by a physician's ownership of his or her own professional practice.

Response: The plain language of the anti-kickback statute is sufficiently broad so as potentially to include payments from a group practice to an investor in the practice, even if the investor is a physician member of the group practice. However, our promulgation of this safe harbor is not an indication that we view investments in group practices as suspect per se under the anti-kickback statute. Similarly, we do not view investments in solo practices as suspect per se.

Comment: Some commenters urged that the proposed safe harbor would have excluded from protection most existing group practices. First, the proposed safe harbor required all investment interests in the group to be held by physicians. ''Investment interests'' was broadly defined to include bonds, notes and other debt instruments. Thus, if a group practice borrowed from a bank or other entity, the bank or other entity would have had an investment interest that precluded safe harbor protection. Second, the proposed safe harbor required all investors to be ''active investors.'' One commenter noted that in most groups, the responsibility for the day-to-day management of the entity is given to one physician or to a practice manager operating under the supervision of a managing physician. This commenter stated that it is not possible or desirable for every physician partner to be responsible for the day-to-day operation of the practice. Another commenter

observed that many group practices are corporations in which the members are shareholders and thus not ''active investors'' in the corporation.

Response: We agree that inclusion of debt interests and the requirement that all investors be ''active investors'' as defined in our investment interests safe harbor unnecessarily limited the proposed group practice safe harbor. The new safe harbor, which applies only to investors who practice in a group practice that meets the group practice definition in the Stark Law, looks only to equity interests owned by physicians for purposes of measuring safe harbor compliance. Moreover, the new safe harbor does not require all group members be ''active investors'' as defined in the small entity investment interests safe harbor. Thus, the fact that all group members do not participate in the day-to-day management of the group practice will not disqualify a group practice from safe harbor protection.

Comment: One commenter expressed concern about the proposed restriction on investment terms being related to the previous or expected volume of referrals, noting that many physicians who previously practiced in solo or small groups have joined group practices or merged into large groups precisely because of the professional relationships between and among the physicians involved.

Response: We agree that a restriction on the terms of an investment interest being related to previous or expected volume of referrals is not necessary in the context of investments in group practices that meet the definition of a group practice under the Stark Law. Our revised safe harbor language does not contain such a requirement. However, the return on the investment interest must comply with the Stark Law, which limits compensation to physician investors that is based on the volume or value of referrals by the physician (section 1877(h)(4)(A)(iv) of the Act and implementing regulations).

Comment: One commenter expressed concern about the prohibition on group practices making loans to, or guaranteeing loans for, investors, if the loans are used to acquire an interest in the group. This commenter believed that this provision could create a problem for physicians who are given the opportunity to buy into an existing practice over time, if a deferred capital contribution were viewed as a loan.

Response: Our new safe harbor does not contain a prohibition on loans from group practices or group practice members used to acquire interests in the group practice.

Comment: One commenter suggested that the safe harbor should be expanded by adding protection for in-office ancillary services (such as a laboratory) shared by physicians who are not part of the same group practice, where the physicians sharing the in-office laboratory bill independently of one another and do not benefit from the volume or value of referrals made by their partners. According to the commenter, these arrangements are common, practical, and cost-effective.

Response: We agree that these arrangements are often practical and cost-effective for physicians. However, as indicated above, we are not prepared to provide safe harbor protection for investments in separately-owned ancillary services at this time, whether the ownership is by group practice members or others. We remain concerned that investments in ancillary services may create incentives for overutilization and lead to increased program costs. This is not to say that all such arrangements are unlawful under the anti-kickback statute. However, we do not believe that it would be possible to craft a sufficiently circumscribed safe harbor that would protect legitimate investments, while at the same time excluding from protection sham investments that are in reality vehicles for the payment of kickbacks.

Comment: One commenter recommended that the safe harbor apply to all practitioners within the reach of the anti-kickback statute, including nurse practitioners, certified nurse-midwives, clinical nurse specialists and certified registered nurse anesthesiologists.

Response: For now, we are limiting the safe harbor to group practices as defined in the Stark Law. The Stark Law definition of group practices applies only to physicians. We may consider an expansion to non-physician practitioners in future rulemaking.

4. Practitioner Recruitment

Summary of Proposed Rule: We proposed a safe harbor for certain payments or benefits offered by rural hospitals and entities in their efforts to recruit physicians and other practitioners. It had come to our attention that some hospitals located in rural areas encounter difficulties in attracting physicians to their communities. Our proposed safe harbor was designed to address this problem without protecting recruitment arrangements intended to channel Federal health care program beneficiaries to recruiting hospitals and entities.

We proposed limiting the practitioner recruitment safe harbor to entities located in rural areas as defined in our proposed safe harbor for investments in rural areas. However, we solicited comments on alternative geographic criteria. One alternative we suggested was limiting safe harbor protection to recruitment of practitioners located in areas that are health professional shortage areas (HPSAs) for the practitioner's specialty category.

To ensure that we did not protect arrangements designed to channel Federal program business to recruiting hospitals or entities, we proposed protecting recruitment of 2 types of practitioners: (1) Practitioners relocating at least 100 miles to a new geographic area and starting a new practice, and (2) new practitioners starting practices or specialties after completing an internship or residency program. We proposed seven standards that would have to be met to qualify for safe harbor protection. We also solicited comments about protecting payments designed to retain physicians already practicing in an area that has been designated as a HPSA for the physician's specialty category.

Summary of Final Rule: The intent of the practitioner recruitment safe harbor is to promote beneficiary access to quality health care by permitting communities that have difficulty attracting needed medical professionals to offer inducements to those professionals without running afoul of the anti-kickback statute. This safe harbor is intended to apply only to areas with a demonstrated need for practitioners and only to practitioners who actually serve the residents of such areas. We are adopting the proposed safe harbor with the following modifications:

- We are expanding the safe harbor to cover practitioner recruitment in urban, as well as rural, underserved areas. Specifically, the safe harbor applies to recruitment activities where the recruited practitioner's primary place of practice will be located in a HPSA for the practitioner's specialty area in accordance with 42 CFR part 5.
- We have eliminated the ''100 mile'' rule.
- We have reduced the required new patient revenues from 85 percent to 75 percent.
- At least 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA or a MUA or who are members of a MUP (as defined by HRSA).
- The benefits may be provided for a term of up to 3 years, provided there is a written agreement, and the benefits do

not directly or indirectly benefit other referral sources. If the HPSA ceases to be a HPSA during the term of the written agreement, the recruitment arrangement will not lose its safe harbor protection.

- The recruited practitioner must agree to treat Federal health care program patients in a non-discriminatory manner.
- We are not requiring the entity doing the recruiting to be located in the underserved area.
- We are not requiring new practitioners to establish staff privileges at the recruiting entity.

Comments and Responses

Comment: Commenters expressed a range of views regarding our proposed definition of ''rural'' for purposes of this safe harbor. Some urged us to adopt the definition of rural used by HCFA to reimburse hospitals located in rural areas under DRG payment rates (42 CFR 412.62(f)(1)(iii)). Others urged that an entity be protected under the safe harbor if it qualifies as a disproportionate share hospital (DSH) under Medicare payment policy. Some commenters suggested that we use HRSA's designations of HPSAs as a means of limiting protection afforded by the safe harbor. Several commenters recommended use of HRSA's designation of MUAs (42 CFR part 51c). One commenter suggested that we substitute a ''demonstrated community need'' standard for the geographic criteria. In addition, many commenters suggested that we extend the practitioner recruitment safe harbor to underserved urban areas. Several commenters proposed that we conform the safe harbor to the Stark Law exception for physician recruitment by eliminating geographic criteria.

Response: We are not prepared to expand this safe harbor by protecting practitioner recruitment wherever it occurs. In many areas, hospitals and other recruiting entities can attract sufficient numbers of qualified practitioners. In such areas, we see no need to protect additional payments or benefits that may in reality be disguised bonuses for high referrers. We recognize, however, that many hospitals in rural and urban underserved areas have legitimate problems attracting physicians and other practitioners and may need to offer additional financial incentives to acquire adequate staff. After carefully reviewing the suggested options, we have concluded that the most sensible approach—one that fairly balances the need to address practitioner shortages with the need to guard against abusive practices—is to extend safe harbor protection to recruitment payments and benefits provided to new and relocating practitioners who establish their primary place of practice in a HPSA in the practitioner's specialty area (see discussion of HPSAs above). The choice of HPSAs has the advantage of (i) including urban underserved areas, which we are persuaded often experience comparable difficulties attracting health care practitioners as rural areas, and (ii) targeting areas that have demonstrated a shortage of practitioners in particular specialties, and, consequently a need for additional recruitment.

We are not adopting the definition of ''rural'' used by HCFA for purposes of reimbursing rural hospitals under DRG payment rates. As discussed above, that definition is derived from the OMB definition of ''rural'' that is used by the Bureau of Census. The OMB methodology is not as closely tailored to the purpose of this safe harbor as is HRSA's HPSA methodology. Moreover, the OMB methodology would not identify underserved urban areas. We also concluded that the use of MUAs would create a broader safe harbor than is needed to facilitate the type of practitioner recruitment we intend to protect. Unlike HPSAs, which target practitioner shortages, MUAs measure shortages of health care services generally.

Similarly, we are not adopting the proposal to use DSH payments as a criterion for safe harbor protection. Although they are an indicator of the number of low-income patients a hospital treats, DSH payments do not necessarily indicate practitioner shortages. A ''demonstrated community need'' standard, while appealing in theory, presents too many difficulties in application to produce consistent and predictable safe harbor protection.

Comment: One commenter asked us to clarify whether the safe harbor protected payments made by recruiting entities that are not located in an rural area to practitioners who are practicing in a rural area. This commenter observed that some hospitals in ''non-rural'' areas serve patients who live in ''rural'' areas.

Response: The safe harbor provides that an entity will be protected if the practitioner's primary place of practice is located in a HPSA for the practitioner's specialty area. Consistent with our intent to facilitate recruitment of health care practitioners to serve the needs of underserved populations, we are not requiring that the recruiting entity also be located in a HPSA.

Comment: One commenter wondered whether a rural referral center (RRC) that had been reclassified by HCFA as urban for purposes of Medicare payment would be eligible for protection under the practitioner recruitment safe harbor.

Response: A RRC recruiting a practitioner whose primary place of practice will be located in a HPSA for the practitioner's specialty area would be eligible for protection under the rural investment interest safe harbor provided it met all of the conditions of the safe harbor.

Comment: The proposed safe harbor applies to new and relocating practitioners who derive 85 percent of their patient revenue from new patients not previously seen by the practitioner at his or her former place of practice. One commenter urged that the threshold be lowered to 50 percent to expand safe harbor protection. One commenter questioned the ability to measure compliance with the 85 percent revenue standard prospectively. Another commenter inquired whether a hospital would be required to audit a recruited physician's practice to ensure compliance with the 85 percent revenue test. One commenter suggested that the 85 percent revenue test be eliminated for urban providers.

Response: A dollar volume standard is necessary to ensure that safe harbor protection is granted only to new practitioners and those genuinely relocating and starting new practices. This safe harbor is intended to protect recruitment activities, not payments to retain physicians in existing practices. The safe harbor does not cover arrangements between hospitals and physicians that may be, in reality, payments to obtain the referrals of established practitioners. However, upon further consideration, we agree that the 85 percent standard we proposed is too high. We are, therefore, lowering the required percentage to 75 percent, which we believe will be sufficient to deter abuses. We recognize that determining compliance with the safe harbor may be problematic in some circumstances, such as during the first year of practice. However, we think that new and relocating practitioners should be able to achieve a reasonable degree of certainty that they have complied with the regulations. Parties to recruitment arrangements may use any reasonable method for establishing compliance, provided they use the same principles consistently over time, so as to avoid manipulating data to obscure noncompliance.

Comment: Several commenters suggested that we use a patient population test instead of a revenue test as a basis for ensuring that the practice is truly new or relocated.

Response: A revenue-based test more accurately measures whether services are, in fact, being provided to new patients than does a test based on the numbers of patients in a practitioner's practice. We do not intend to protect relocating practitioners who establish practices in HPSAs, but who continue primarily to treat patients from the practitioner's former practice.

Comment: The proposed safe harbor contained a requirement that a relocating practitioner's physical primary place of practice be at least 100 miles from his or her previous primary place of practice. Several commenters urged us to eliminate the 100 mile rule altogether or reduce the distance required. These commenters pointed out that the 100 mile requirement would produce arbitrary results in some circumstances and that some rural areas with practitioner shortages were located less than 100 miles from urban areas with pools of potential practitioners from which to recruit. Moreover, the 100 mile rule made it more difficult for urban undeserved areas to qualify for safe harbor protection. One commenter suggested using a travel distance of one and a half hours as a means of ensuring a majority of the practitioner's patients will be new. In the alternative, a commenter suggested making the 100 mile rule an alternative test to the 85 percent new patient revenue rule.

Response: The 100 mile rule was intended to ensure that the safe harbor protected recruitment of new or relocating practitioners only. However, we are persuaded that the proposed 100 mile rule would be impractical and lead to arbitrary results in some circumstances and would unnecessarily limit the protection afforded by this safe harbor. We also recognize that the 100 mile rule would make it difficult for entities in urban underserved areas to enter into recruitment arrangements that qualify for the safe harbor. Accordingly, we are eliminating the 100 mile rule, thereby enabling some recruitment arrangements to qualify for the safe harbor even if the practitioner relocates his or her primary place of practice only a short distance to a HPSA.

We are concerned, however, about the possibility of abuse by experienced practitioners, particularly in urban settings, who may ''relocate'' their offices short distances to underserved areas in order to qualify for the safe harbor and therefore receive recruitment payments that may, in fact, be rewards for referrals. The 75 percent new patient revenue test does not adequately guard against such abuse, because it measures whether patients are new to the practice and not whether patients are part of an underserved population. To ensure that safe harbor protection is not available for practitioners who relocate but do not serve the populations intended to benefit from this safe harbor, we are adding a requirement that 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA or a MUA or who are members of a MUP. The patients do not necessarily have to reside in the specific HPSA in which the practitioner's new practice is located, but may reside instead in a nearby MUA or HPSA. In sum, to qualify for the safe harbor, a new or relocating physician must substantially treat patients who are new to the physician's practice and who reside in underserved areas, or are members of medically-underserved populations designated by HRSA.

Comment: A number of commenters discussed the third proposed safe harbor standard, which would have imposed certain time limits on payments and benefits protected by the safe harbor. One commenter recommended extending the time limit for protected recruitment payments in non-HPSA rural areas from 3 years to 5 years. Several commenters urged us to allow protected recruitment payments for practitioners in HPSAs for as long as an area is designated as a HPSA. Some commenters questioned what would happen if a HPSA designation was revoked during the term of the recruitment contact. These commenters recommended that the contract continue to be protected for its term.

Response: Our original proposed safe harbor contemplated a 3 year limit on benefits, unless the practitioner was located in a HPSA, in which case recruitment benefits would be protected for the entire duration of the relationship between the practitioner and the recruiting entity. Given that we have limited the scope of this safe harbor to HPSAs, the 3 year limit for non-HPSA rural areas originally proposed no longer pertains.

However, our experience over the past few years has shown that practitioner recruitment is an area frequently subject to abusive practices. The risk of kickbacks is mitigated when payments are made to new or relocating physicians who do not have established referrals streams that can be locked up through inappropriate incentives and loyalties. Thus, we have concluded that protected payments under this safe harbor should not be of unlimited duration or subject to renegotiation that may be based on the volume or value of referrals. We believe that 3 years is a reasonable time period for recruitment benefits. Accordingly, we are amending the third standard to read as follows: ''the benefits are provided by the entity for a period not to exceed 3 years, and the terms of the agreement are not renegotiated during this 3 year period in any substantial aspect.'' By ''any substantial aspect,'' we mean in any manner that materially affects the payments and benefits to be made to the recruited practitioners under the written agreement. We have also revised the safe harbor to make clear that if the HPSA designation is revoked during the term of the contract, the payments will remain protected for the term of the contract (which term may not exceed 3 years), provided all other safe harbor conditions are satisfied.

We understand that limiting recruitment payments and benefits raises the question of incentives to retain physicians in HPSAs beyond an initial 3 year period. Because of the increased risk of kickbacks, payments for retention purposes require closer scrutiny than initial recruitment payments. We solicited comments regarding development of a physician retention safe harbor. We received several comments in support of such a safe harbor. A physician retention safe harbor may be the subject of future rulemaking.

Comment: Several commenters had concerns about the fourth proposed standard of the physician recruitment safe harbor, which would require that ''the entity providing the benefits cannot condition the agreement on the practitioner's referral of business to the entity.'' Specifically, one commenter inquired if this meant that the hospital could not condition the recruitment payments on the practitioner having and maintaining staff privileges at the recruiting entity.

Response: This requirement is derived from the small entity investment interests safe harbor at § 1001.952(a)(2)(iv) and is intended to ensure that the agreement is not conditioned on the referral of business from the practitioner to the entity. Consistent with this provision, hospitals may require a practitioner to have and maintain staff privileges; however, a hospital may not prohibit the practitioner from obtaining or maintaining staff privileges at other facilities. A hospital may not condition recruitment payments on aggregate admissions by the practitioner, nor may it require a recruited practitioner to admit a proportionate share of his or her patients to the hospital. A hospital may impose conditions intended to ensure quality of patient care, such as requiring that a physician have performed a minimum number of a particular type of

procedure before performing the procedure at the hospital.

Comment: Some commenters questioned the need for the requirement that practitioners agree to treat Medicare and Medicaid patients. One commenter suggested that the regulations require a recruited physician to treat all patients referred by the hospital, regardless of a patient's insurance status or ability to pay. A similar comment suggested that the regulations for physician recruitment require the physician to become a participating provider in the Medicare and Medicaid programs.

Response: We have generally addressed this issue in our discussion above. To impose a standard requiring a practitioner to treat all patients referred by a hospital would exceed our regulatory authority. Likewise, we are not requiring recruited practitioners to become participating providers in the Medicare and Medicaid programs. However, if they participate in any Federal health care program, they must treat all program beneficiaries in a nondiscriminatory manner.

Comment: A number of commenters requested that we further define the terms ''payment'' and ''benefit'' as used in §§ 1001.952(n)(1), (3), and (6) of the proposed physician recruitment safe harbor. Some commenters sought guidance regarding which specific payment practices are protected by the safe harbor.

Response: We decline to specify in these regulations any particular set of payment practices covered by this safe harbor. Recruitment practices necessarily vary depending on specific circumstances. Accordingly, whether payment practices are protected by this safe harbor must be evaluated on a case-by-case basis. In particular, the amount or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to, or business otherwise generated for, the recruiting entity by the practitioner for which payment may be made in whole or in part under a Federal health care program.

Comment: A commenter urged that the final regulations make clear that compliance with the recruitment safe harbor exempts parties from having to comply with other safe harbor regulations, including the personal services, space and equipment rental and obstetrical malpractice insurance safe harbors.

Response: This comment addresses a situation where a recruitment agreement may involve more than one safe harbor (*e.g.*, the space rental and obstetrical malpractice safe harbors). If the recruitment agreement as a whole meets the criteria of the recruitment safe harbor, then the agreement as a whole is exempt from criminal prosecution. If, however, the agreement does not fit within the recruitment safe harbor, certain payments made in accordance with it may still be protected under the other safe harbors, if the other individual safe harbor criteria are met.

Comment: Several commenters requested that we clarify whether the safe harbor protects joint recruitment efforts between hospitals and group practices or between hospitals and individual physicians who may employ new physicians in their practices. Along these same lines, one commenter asked us to protect the indirect recruitment activities of managed care organizations, which frequently conduct physician recruitment in conjunction with participating hospitals.

Response: We are aware that an increasing amount of physician recruitment is being conducted through joint arrangements between hospitals and group practices or solo practitioners. Typically, these arrangements involve payments from hospitals to group practices or solo practitioners to assist the group practice or solo practitioner in recruiting a new physician. Managed care organizations are also involved in joint practitioner recruitment activities with hospitals and physician practices. On the one hand, these arrangements can be efficient and cost effective means of recruiting needed practitioners to an underserved community. Moreover, many new practitioners prefer joining an existing group practice to starting a solo practice. On the other hand, these arrangements can be used to disguise payments for referrals from the group practice or solo practice to the hospital.

We are not persuaded that a safe harbor can be crafted that would protect legitimate joint recruiting arrangements of the type described above without sweeping in sham arrangements that are actually disguised payments for referrals. However, we want to make clear that joint recruitment arrangements are not necessarily illegal and must be evaluated on a case-by-case basis. Parties seeking further guidance about their joint recruitment activities may apply for an advisory opinion.

Comment: One commenter stated that the sixth standard of the proposed safe harbor for physician recruitment, which prohibits benefits that vary based on the volume or value of expected referrals, would eliminate income guarantees from safe harbor protection, since the amount of the funds advanced against the guarantee are generally not determined until the new physician has commenced his or her practice and the initial income from the practice has been determined. According to the commenter, income guarantees are among the most common recruitment incentives.

Response: The anti-kickback statute prohibits payment of any remuneration to induce referrals for which payment may be made in whole or in part by a Federal health care program. To this end, this safe harbor, like others, prohibits payments that are based on the volume or value of expected referrals. Recruitment incentives tied to volume or value of referrals generated are not immunized by this safe harbor. However, where the maximum amount of the income guarantee and the formula for determining payment under the guarantee are set in advance and not subject to renegotiation, the formula is not tied to volume or value of referrals, and the income guarantee otherwise meets the safe harbor requirements, the fact that the actual amount that will be paid to the practitioner under the guarantee is not known in advance will not disqualify the income guarantee from safe harbor protection.

Comment: One commenter requested clarification as to how the recruitment safe harbor would apply to physicians recruited to fill medical director positions where, in most cases, the physician is not an employee of the facility and is not generally perceived as a source of referrals.

Response: In many circumstances, medical directors are potential referral sources and medical director contracts serve as a means to reward referrals. There is no special protection for medical directors under the practitioner recruitment safe harbor. To be protected, a recruitment arrangement must meet all of the standards of the safe harbor, including the new patient and underserved patient revenue tests (§§ 1001.952(n)(2) and (8)). In the alternative, a contract for medical director services may qualify for protection under the employee compensation or personal services contract safe harbors (§§ 1001.952(i) and (d)).

Comment: Several commenters urged us to make the safe harbor consistent with IRS Revenue Ruling 97–21 on physician recruitment.

Response: The IRS Revenue Ruling 97–21 on physician recruitment by a tax-exempt hospital is intended to provide guidance on recruitment activities that are consistent with a hospital's operations as a tax-exempt entity. The revenue ruling sets forth standards for determining whether a

tax-exempt hospital's practitioner recruitment activities jeopardize its tax-exempt status. Under the revenue ruling, a hospital does not jeopardize its tax-exempt status if its recruitment payments are reasonably related to its tax-exempt purpose. However, this standard is an insufficient safeguard against improper payments for referrals. A payment that is reasonably related to a hospital's tax-exempt purpose, but is tied to the volume or value of expected referrals, will likely run afoul of the anti-kickback statute and is not appropriate for safe harbor protection.

Comment: One commenter asked us to reaffirm that not all physician recruitment activities necessarily violate the anti-kickback statute, and that recruitment programs not meeting the safe harbor criteria will be analyzed on a case-by-case basis.

Response: The failure of a particular arrangement to comply with the safe harbor does not determine whether or not the arrangement violates the anti-kickback statute. Neither does such failure determine whether an enforcement action is warranted. As a general rule, remuneration to physicians, including recruitment, should be consistent with fair market value for necessary services rendered by the physician. The practitioner recruitment safe harbor protects certain payment practices that may depart from this general rule if particular criteria established by the safe harbor are met. Arrangements that do not qualify for the safe harbor must be evaluated on a case-by-case basis to determine whether there has been a violation and whether an enforcement proceeding is warranted.

5. Obstetrical Malpractice Insurance Subsidies

Summary of Proposed Rule: We proposed a new safe harbor to permit a hospital or other entity to pay all or part of the malpractice insurance premiums for practitioners engaging in obstetrical practice in primary health care professional shortage areas. For purposes of this safe harbor, we included certified nurse midwives as defined in section 1861(gg) of the Act in the definition of ''practitioner.'' We limited this safe harbor to the provision of malpractice insurance regulated by State law. We explained that nothing in the safe harbor would authorize payment by the Federal health care programs to hospitals or other institutional providers for costs they may incur in providing malpractice insurance. Any allowable costs for such insurance are governed strictly by Federal health care program rules.

We solicited comments on specific, narrowly-drawn circumstances where this safe harbor provision could be expanded to help assure beneficiary access to services that may be significantly affected by the cost of malpractice insurance premiums. In addition, we solicited views regarding the feasibility of expanding this safe harbor to protect malpractice insurance programs that are not regulated under State law, but which are operated directly by providers.

Summary of Final Rule: This safe harbor is intended to facilitate access to obstetrical services for Federal health care program beneficiaries in primary care health professional shortage areas by protecting from the reach of the anti-kickback statute subsidized malpractice insurance for practitioners who are primarily engaged in obstetrical practices in those areas. We have adopted the proposed safe harbor with the following modifications:

- We are expanding the safe harbor to cover self-funded insurance plans.
- We are reducing from 85 percent to 75 percent the proportion of the practitioner's obstetrical patients who must be treated under the subsidized insurance coverage.
- We are eliminating the phrase ''be in a position to make or influence referrals'' from § 1001.952(o)(3), since most, if not all, insurers require practitioners to be in a position to perform obstetrical services as a condition of coverage.
- We are requiring that protected practitioners be engaged in obstetrics as a routine part of their practices. Full subsidies for obstetrical malpractice insurance may be paid for full-time obstetricians or nurse midwives; for part-time practitioners in obstetrics, the safe harbor protects only costs attributable to the obstetrical portion of their practices.

Comments and Responses

Comment: One commenter recommended expanding the phrase ''practitioners engaging in obstetrical practice'' to include explicitly family practitioners and other physicians who may deliver babies, in order to make clear that the safe harbor covers insurance subsidies for such individuals.

Response: We agree that limited safe harbor protection is appropriate for family practitioners and other physicians and certified nurse midwives who deliver babies as a routine part of their medical practices. Accordingly, we are amending the proposed regulation to provide for limited coverage for ''a practitioner who engages in obstetrical practice as a routine part of his or her medical practice.'' For purposes of this safe harbor, by ''routine'' we mean that the practitioner must provide substantial and regular obstetrical services; we do not intend to protect obstetrical insurance subsidies for practitioners who practice obstetrical medicine on only an occasional basis.

For practitioners who are not full-time obstetricians or certified nurse midwives, we will protect payments for *obstetrical* malpractice insurance only. We will not protect subsidies for other types of medical malpractice liability insurance. Thus, for these practitioners the protected subsidy will be the difference between the cost of malpractice insurance that includes obstetrical coverage and the cost of malpractice insurance that does not include such coverage. Similarly, the safe harbor will protect certain insurance subsidies paid on behalf of practitioners engaged in obstetrical practices part-time in a HPSA and part-time elsewhere. We have in mind, in particular, urban obstetricians who may practice several days in an inner-city clinic (in a HPSA) and several days in areas that are not underserved. For these practitioners, the safe harbor protects insurance subsidies for obstetrical malpractice insurance coverage related exclusively to services provided in the HPSA. If the practitioner is covered by a single insurance policy or program, the safe harbor covers subsidies for that portion of the insurance premium that is reasonably allocable to obstetrical services provided in a HPSA.

Comment: We solicited comments on specific, narrowly-drawn circumstances where this safe harbor provision could be expanded to help assure beneficiary access to services that may be significantly affected by the cost of malpractice insurance premiums. In response, one commenter recommended expanding this safe harbor to include neuro, cardiovascular and orthopedic surgeons. Two commenters recommended enlarging the safe harbor to cover malpractice insurance coverage for pediatricians. A commenter also recommended expanding the safe harbor to cover emergency room coverage by high risk medical specialists in situations where a hospital is able to certify that a viable panel of specialists is only possible if the hospital can provide this benefit. One hospital association expressed concern that a safe harbor only for insurance subsidies for obstetrical practitioners may create unnecessary concern in the industry that all other types of practitioner malpractice insurance subsidies may be suspect. The

association recommended greatly expanding the proposed safe harbor or deleting it as written.

Response: This safe harbor is intended to promote access to obstetrical services for Federal health care program beneficiaries and others in underserved areas. Although we solicited comments on expanding this safe harbor, we are not persuaded at this time that there are compelling reasons to expand it beyond malpractice insurance subsidies for practitioners engaging in obstetrical practices. This safe harbor does not call into question the legality of all other types of practitioner malpractice insurance subsidies. Such subsidies may qualify for protection under other safe harbors, such as practitioner recruitment, personal services contracts or employee compensation (§§ 1001.952(n), (d), and (i)). Moreover, as we have previously stated, the fact that a payment practice does not fall within the ambit of a safe harbor does not necessarily mean that the practice violates the anti-kickback statute. At the same time, we note that malpractice insurance subsidies paid to or on behalf of potential referral sources may be suspect under the anti-kickback statute. These arrangements are subject to a case-by-case evaluation. The advisory opinion process is available for parties seeking OIG guidance on the anti-kickback implications of particular insurance subsidy arrangements (See 42 CFR part 1008).

Comment: Several commenters offered views on the geographic scope of the safe harbor. One commenter recommended that we expand the scope of the safe harbor to protect subsidies in primary care HPSAs and in rural areas as defined in 42 CFR 412.62(f)(1)(iii). Another urged application of the safe harbor in urban areas. Some commenters noted that the HPSA designation process is a volatile, on-going process, and that the list of shortage areas is rarely an accurate reflection of actual need for health care professionals at a particular point in time. Moreover, these commenters believed that dependence on Federal designations fails to recognize the role of states in identifying and remedying health professional shortage areas. One commenter suggested focusing on emergency room admissions of obstetrics patients who have no designated primary care practitioner rather than on HPSA data to measure community need.

One commenter raised the question of what happens when the offer of subsidized malpractice insurance induces a physician to relocate to a HPSA, but the physician's relocation itself serves to remove the community's HPSA designation. This commenter proposed substituting a ''need'' standard, with the appropriate documentation of need for the subsidized practitioner left up to the entity providing the subsidy. This commenter observed that many current safe harbors use the concept of ''fair market value'' without requiring any particular fair market value standard to be met, and the health care community for the most part understands that documentation is critical to prove fair market value in the event a particular transaction is later scrutinized. Examples of documentation of ''need'' could include determinations by State legislatures, as well as any other appropriate indications of need for a particular type of health care professional.

Response: As described in greater detail above in our responses to comments on the practitioner recruitment safe harbor, primary care HPSAs may be located in rural or urban areas. We are limiting this safe harbor to primary care HPSAs so as to ensure as much as possible that the benefits protected by this safe harbor are extended to practitioners in areas where there is a well-founded, documented shortage of obstetrical practitioners. We are aware that there are and have been problems with the HPSA process. We expect that the Department's anticipated revision of the process should address many of those problems, including providing States with greater input in designating shortage areas. We believe that a general ''need'' standard could be manipulated in ways that would permit abusive payments in the guise of insurance subsidies. We note that nothing in this safe harbor prevents protection of malpractice insurance subsidies for practitioners engaged in practice outside primary care HPSAs as part of an arms-length, fair market value compensation package that meets the requirements of the personal services safe harbor or the employee compensation exception to the anti-kickback statute (§§ 1001.952(d) and (c); 42 U.S.C. 1320a–7b(b)(3)(B)).

Comment: One commenter questioned the feasibility of the requirement that 85 percent of the practitioner's obstetrical patients treated under the insurance coverage must come from certain defined underserved populations, noting that compliance with the standard can only be determined after the payment of the insurance premium subsidy. The commenter observed that obtaining liability coverage necessarily precedes treatment of any patients under that coverage. Documenting compliance with the standard is particularly problematic where insurance subsidies are used as recruiting devices for new or relocating practitioners who do not have established patient pools that can be measured. One commenter suggested that this problem could be solved by deeming the 85 percent test satisfied if the practitioner provides a written stipulation that the 85 percent test will be met.

Response: Upon further review, we believe that an 85 percent test is unnecessarily restrictive. Accordingly, we have amended the safe harbor to provide that 75 percent of the patients treated must come from underserved populations, that is, they must reside in a HPSA or a MUA or be part of a MUP, all as defined by HRSA and described above. Moreover, we agree that under the test as drafted in the proposed rule, it would not be possible for parties seeking safe harbor protection to determine whether a payment for an insurance subsidy satisfies the safe harbor prior to making the payment. However, we believe that a practitioner stipulation is insufficient by itself to ensure that appropriate populations are benefitting from the increased access to obstetrical care contemplated by this safe harbor. Accordingly, we have amended the safe harbor to provide that for the initial coverage period, which will be limited to one year, the practitioner must certify that he or she has a reasonable basis for believing that he or she will meet the 75 percent test for the duration of the coverage period. Thereafter, for payments of insurance premiums to be protected, the 75 percent standard must have been met for the period covered by the preceding insurance premium payment, which coverage period may not exceed one year.

Comment: One commenter recommended eliminating the requirement that the insurance subsidy be paid to the insurance provider, rather than the subsidized practitioner.

Response: The requirement that the subsidy be paid to the insurance provider is a reasonable means of ensuring that the payment is used for the purposes intended by this safe harbor. Permitting a direct cash payment to the subsidized practitioner increases the risk that the ''subsidy'' payment may in fact be a disguised payment for referrals. We are not persuaded that payment directly to insurance providers is impractical or unduly burdensome on subsidizing entities or subsidized practitioners.

Comment: One commenter believed that the requirement that practitioners

treat Medicaid patients is superfluous, because the anti-kickback statute is only implicated where Medicaid and Medicare referrals are in fact made. Another commenter recommended amending the requirement to provide that a physician may not discriminate against Medicaid patients to the extent the physician is able to see new patients in his or her practice. Otherwise, the safe harbor would preclude protection for physicians whose current practices may be full.

Response: These issues are addressed above with respect to the safe harbor regarding physician recruitment.

Comment: A commenter observed that some professional liability underwriters, especially in states with harsh liability climates, do not have the surpluses required to provide coverage beyond certain minimum limits, and suggested that the safe harbor should protect hospital underwriting of all physician liability above certain limits in order to protect physicians against large awards against them. The commenter suggested limits of $100,000 to $300,000.

Response: This proposal, which essentially would cover the entire range of practitioner services, does not meet our requirements for proposals of specific, narrowly-drawn circumstances where the safe harbor could be expanded to help assure beneficiary access to services significantly affected by the cost of malpractice insurance premiums.

Comment: Several commenters suggested the safe harbor be extended to protect payment of premiums or establishment of reserves in self-funded programs underwritten and operated by hospitals and other providers, including risk-retention groups. These commenters point out that many hospitals and other entities elect self-insurance programs for physicians on the medical staff, instead of purchasing commercial insurance from independent third parties. The commenters noted that self-insurance programs, including risk-retention groups, were established in response to the unavailability or unaffordability of malpractice insurance for certain areas or specialities. Commenters believed that these programs keep health care costs to a more reasonable level and ought to be encouraged and protected. They argued that the benefit to the physician is the same whether insurance is provided through a self-funded program or commercial third party insurance, and thus hospitals or other health care providers with self-funded programs should not be deprived of protection. Self-insured hospitals are not in a position to make payments to another entity that provides insurance. To assure that only *bona fide* programs are shielded, one commenter recommended that only programs that have been certified by a qualified actuary as adequate relative to the risk assumed should be afforded safe harbor protection. Finally, several commenters suggested expanding the safe harbor to include offshore insurance products.

Response: We solicited comments regarding the feasibility of expanding the safe harbor to protect subsidies for insurance under programs operated directly by providers. As indicated in the preamble to the 1993 proposed rule, our concern was that the subsidized insurance policies be *bona fide* to ensure that this safe harbor is not used as a mechanism to disguise improper inducements to practitioners. The requirement that the insurance be *bona fide* also protects practitioners and patients. We agree that from the practitioner's perspective, the benefit derived from an insurance subsidy is the same whether the insurance is provided by commercial third party insurance or a self-funded program. Accordingly, we have amended the safe harbor to extend protection to *bona fide* self-funded obstetrical malpractice insurance programs, including risk-retention groups that qualify under the Liability Risk Retention Act, 15 U.S.C. 3901, and to *bona fide* offshore insurance products. Although we are not defining the full scope of *bona fide* insurance products, we believe that certification by a qualified actuary that the program is adequate relative to the risk insured would be an indicator of a *bona fide* insurance program.

Comment: One commenter suggested that the prohibition on requiring a physician to ''be in a position to make or influence referrals'' limits the ability of facilities to require that physicians maintain medical licenses and be in a position to practice medicine and recommended that the prohibition be eliminated.

Response: Nothing in these safe harbor regulations is intended to prevent hospitals and other health care facilities from requiring that physicians and other practitioners who perform services at or for such facilities be fully licensed and able to practice medicine. In particular, we recognize that proper licensure and qualifications to practice medicine are prerequisites for obtaining malpractice insurance. We are persuaded that the language ''be in a position to make or influence referrals to'' is unnecessary in the context of a safe harbor for obstetrical malpractice insurance subsidies. Therefore, we have amended the third condition of the safe harbor to prohibit any requirement that practitioners ''make referrals to, or otherwise generate business for, the entity as a condition for receiving the benefits.''

Comment: One commenter expressed concern that the safe harbor does not adequately protect group practices.

Response: A group practice that provides obstetrical malpractice insurance subsidies may qualify as an ''entity'' for purposes of this safe harbor. Moreover, as indicated above, we have amended the safe harbor to permit entities to subsidize insurance through self-funded insurance programs. This safe harbor is not intended to protect group practices for any payment practice that does not satisfy all of the safe harbor criteria, including the requirements that the subsidized practitioner practice in a primary care HPSA and that 75 percent of the obstetrical patients treated reside in underserved areas.

6. Referral Agreements for Specialty Services

Summary of Proposed Rule: We proposed a new safe harbor for referral agreements for specialty services. This safe harbor would protect arrangements under which an individual or entity agrees to refer a patient to another individual or entity for specialty services in return for an agreement on the part of the party receiving the referral to refer the patient back at a certain time or under certain circumstances. For example, a primary care physician and a specialist (to whom the primary care physician has made a referral) may agree that, when their patient reaches a particular stage of recovery, the primary care physician should resume treatment of the patient.

We proposed three standards that such a referral arrangement would have to meet to fit within the safe harbor. First, the service for which the initial referral is made must not be within the medical expertise of the referring party and must be within the special expertise of the party receiving the referral. Second, the parties could receive no payment from each other for the referral. Third, the only exchange of value permitted between the parties would be the monetary remuneration each party would receive directly from third-party payers or the patient as compensation for professional services furnished by each party to the patient.

We proposed an accommodation in this safe harbor for members of the same group practice who refer to one another. Where the referring and receiving physicians belong to the same group practice, revenues are shared among

members of the group practice, and thus it appears that the referring physician receives remuneration for the referral. However, such financial benefits are an inherent part of belonging to a group practice, and therefore we proposed protecting such remuneration if the group practice met the definition of ''group practice'' in section 1877(h)(4) of the Act.

Summary of Final Rule: Because of the potential for abuse when the referring physician and the specialty physician receiving the referral split a global payment from a Federal health care program, we are revising the regulation specifically to exclude remuneration received in such circumstances from the safe harbor. We are also adding a requirement that the condition for the referral back to the originating referral source must be clinically appropriate. We are otherwise promulgating the safe harbor as proposed.

Comments and Responses

Comment: A number of commenters generally supported the approach of the proposed safe harbor, stating that it would adequately protect legitimate referral arrangements while sufficiently discouraging illegitimate ones. They suggested that the safe harbor would be useful because it would assure convenient access to follow-up care in communities where there are no specialists. However, several commenters suggested that insulating referrals for specialty services from the kickback statute would encourage arrangements that might compromise the quality of patient care, because arrangements between the primary physician and the referral specialist might require a patient to be referred back to the primary physician, regardless of whether it would be clinically appropriate. Further, specialty referral arrangements could deny patients the right to choose their providers.

Response: We share the commenters' concerns that patient referrals be made only under clinically appropriate circumstances. Indeed, clinical appropriateness should be the touchstone of all referrals, specialty or otherwise. To emphasize the importance of clinical appropriateness as a consideration, we are revising the safe harbor to reflect that the ''mutually agreed upon time or circumstance'' for the receiving specialist to return the patient must be clinically appropriate. We are not further defining ''clinically appropriate,'' however, because whether a referral is clinically appropriate will depend on the particular facts and circumstances. Depending on circumstances, an agreement to refer a patient back on a date certain, without regard to medical condition, would be questionable.

We also share the commenters' concerns regarding the preservation of patient freedom of choice. Patient freedom of choice may be compromised, however, if patients are not given access to needed specialty care. There is a legitimate concern if physicians are disinclined to refer patients to specialists because of fear of losing patients to those specialists permanently. Thus, for example, the safe harbor would protect an agreement between a general cardiologist and a cardiologist with special expertise on a particular medical condition whereby (i) the general cardiologist would refer a patient to the specialist for treatment of the particular medical condition about which the specialist has expertise, and (ii) the specialist—who also has a general cardiology practice—would refer the patient back to the originating cardiologist upon completion of the specialty treatment.

We want to make clear that protection under this safe harbor is limited to referral arrangements for patients of the physician making referrals to the specialist. The safe harbor does not protect generalized cross-referral arrangements of the ''you send me your patients and I'll send you mine'' variety. Rather, the safe harbor protects an agreement to refer patients to a specialist in return for an agreement or understanding that the specialist will refer those *same* patients back at the agreed upon time or circumstance (*e.g.*, completion of the specialist services for which the patient was referred). In other words, assuming all safe harbor conditions are satisfied (and there is no split of a global fee, as discussed below), the safe harbor will protect agreements along the lines of ''I'll send you my patients who need your specialist services if you agree to send them back to me upon completion of your services.''

On balance, we believe that a safe harbor under the anti-kickback statute for referrals for specialty services is appropriate and will protect many legitimate referral arrangements that benefit patients, including those living in remote areas. Where no payment is made between the referring and receiving parties (and there is no splitting of a Federal health care program global fee, as discussed below), we believe the specialty referral arrangements protected by the safe harbor pose no more than a minimal risk of illegal remuneration for referrals in violation of the anti-kickback statute.

Comment: Ophthalmology providers were especially concerned that the proposed safe harbor may encourage the development of potentially abusive referral arrangements with optometrists, who wish to receive the post-operative portion of the Medicare global fee for eye surgery. The ophthalmologists allege that many optometrists refer patients to ophthalmologists on the condition that patients be referred back to the optometrists for post-surgical care, often without regard to clinical appropriateness. Some ophthalmologists claimed that optometrists generally control referrals and therefore ophthalmologists, for whom surgical procedures are the mainstay of their practices, must acquiesce to these return referral arrangements in order to get patients. One commenter described a situation where an optometrist/ophthalmologist network referred patients for cataract surgery only to ophthalmologists who would agree to split the global surgical fee by referring the patient back to the optometrist for post-operative care. The optometrists referred their patients to an ophthalmologic surgery center 200 miles away when there were at least 50 available ophthalmologists from 7 to 35 miles away. In such circumstances, the ophthalmologists do not do any of the follow-up care for the patients and the post-operative portion of the global fee is paid to the optometrists. The commenter, an ophthalmologist, had provided some of the patients referred by the optometrist network with a second opinion and found that none required surgery.

Response: The serious issues raised by the ophthalmologists about apparently routine or blanket agreements to split global Medicare fees with referring optometrists (as well as other information that has come to our attention from industry and Government sources) has caused us to modify the scope of this safe harbor. We have revised the safe harbor regulation to preclude protection for arrangements between parties that share or split a global or bundled payment from a Federal health care program for the referred patient. Thus, for example, the safe harbor does not protect referral arrangements where the parties bill Medicare using the 54/55 modifiers to indicate an 80 percent-20 percent split of the surgical fee for cataract surgery.

By limiting the safe harbor, we do not mean to suggest that all specialty referral arrangements involving splitting of global fees are illegal under the anti-kickback statute. Whether a particular

referral arrangement for specialty services violates the anti-kickback statute depends on a case-by-case analysis of all of the facts and circumstances, including, but not limited to, whether the specialty services are medically necessary, whether the timing of the referrals is clinically appropriate, and whether the services performed are commensurate with the portion of the global fee received.

Comment: One commenter questioned whether the anti-kickback statute applies to specialty referral arrangements where no kickback, rebate or other consideration is made for the referral.

Response: As the United States Court of Appeals for the First Circuit has recognized, the opportunity to generate a fee may constitute the requisite remuneration under the statute, even if no payment or rebate is paid for a referral. For instance, the opportunity to split a global surgical fee, as in the hypothetical described in the previous comment, is an example of a circumstance in which an opportunity to generate a fee is something of value to a referring party apart from any payment for the referral. Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare patients toward a particular recipient. (See *United States* v. *Bay State Ambulance and Hospital Rental Service, Inc.,* 874 F.2d 20, 29 (1st Cir. 1989)).

Comment: A managed care organization trade association commented that managed care organization arrangements often require the referral of patients to other contracting providers as a condition of the provider's compensation and that the anti-kickback statute should not be construed so broadly as to encompass these types of managed care arrangements. In addition, a managed care plan commented that the safe harbor should be expanded to exempt expressly referrals made within an HMO, or that the OIG should establish a new safe harbor for referrals made by HMO-participating physicians.

Response: The anti-kickback statute is broad and technically may cover many managed care arrangements that are common in the marketplace today. However, we have recognized that most of these arrangements involving HMOs do not create the potential for fraud or abuse and have created safe harbors aimed at those arrangements. Currently, § 1001.952(m) protects certain price reductions offered to health plans. In addition, as part of HIPAA, Congress enacted a statutory exception for managed care arrangements that put individuals or entities at substantial financial risk (42 U.S.C. 1320a–7b(b)(3)(F)).[5] These safe harbors offer broad protection under the anti-kickback statute to HMOs.

Comment: One commenter urged that we clarify the safe harbor to make clear that it covers primary care practitioners in rural areas who do not belong to group practices.

Response: The safe harbor applies to solo practitioners, as well as members of group practices. To be protected by the safe harbor, solo practitioners may not give anything of value to a specialist in exchange for the referral back of his or her original patient, except for the opportunity to receive compensation for services directly from third parties or patients. Members of *bona fide* group practices who refer among themselves are not similarly restricted; they may share revenues from specialty services performed as a result of the intra-group referrals.

7. Cooperative Hospital Service Organizations

Summary of Proposed Rule: We proposed a new safe harbor to protect cooperative hospital service organizations (CHSOs) that qualify under section 501(e) of the Internal Revenue Code. These organizations are formed by two or more tax exempt hospitals (known as ''patron hospitals'') to provide specifically enumerated services, such as purchasing, billing, and clinical services solely for the benefit of patron hospitals. These entities are required by law to distribute all of their net earnings to patrons on the basis of services performed (26 U.S.C. 501(e)(2)).

The safe harbor would protect payments from a patron hospital to a CHSO to support the CHSO's operational costs and those payments from a CHSO to a patron hospital that are required by IRS rules. As a condition of protection, the CHSO must be wholly owned by its patron hospitals, in order to avoid potentially abusive joint venture arrangements formed under the guise of CHSOs. To the extent a CHSO acts as a group purchasing agent or a patron hospital obtains discounts as a result of the CHSO's activities, CHSOs and patron hospitals must comply with the respective safe harbor provisions applicable to group purchasing organization and discounts (§§ 1001.952(j) and (h)) to be fully protected. We solicited comments regarding the various types of payment formula (which comply with the IRS rules) that are used by CHSOs, but did not receive any comments on this issue.

Summary of Final Rule: We are adopting the rule as proposed, with some minor technical changes.

Comments and Responses

Comment: We requested comments on the extent to which we should expand this provision to protect other similar entities specifically organized under Federal or State laws. Four comments were submitted suggesting that the safe harbor be expanded to include other types of cooperative organizations that qualify under subchapter T of the Internal Revenue Code (sections 1381 to 1388). One commenter also requested that the safe harbor be expanded to include other types of hospital cooperative organizations.

Response: We decline to extend safe harbor protection to cooperative organizations that do not qualify under section 501(e). Unlike CHSOs complying with that section, there are few limitations applicable to cooperative organizations qualifying under subchapter T. There are no limits on the types of services that may be shared, nor are there restrictions on the identity of shareholders. The conditions and limitations imposed on tax-exempt entities, including the limits on private inurement, do not apply to subchapter T organizations. We believe the limitations imposed under section 501(e) are necessary to protect against potentially abusive joint ventures or referral arrangements. Additionally, in view of the small number of comments we received concerning non-hospital cooperatives and the fact that we received only a single comment requesting broader hospital coverage, we are not persuaded of the need to broaden the safe harbor to other types of hospital or non-hospital cooperatives. Accordingly, we are adopting the proposed safe harbor for CHSOs without modification.

8. Modification of Sale of Practice Safe Harbor

Summary of Proposed Rule: We solicited comments on the desirability of modifying the existing sale of practice safe harbor set forth in § 1001.952(e) to accommodate transactions involving the rural hospital purchase of a physician practice as part of a practitioner recruitment program that complies with the safe harbor we are establishing to protect practitioner recruitment. The existing sale of practice safe harbor did not protect such purchases. We had been informed that many rural hospitals buy and ''hold'' the practice of a retiring physician, often using *locum tenens*

[5] See footnote 2.

physicians until a new physician can be recruited to replace the retiring one.

Summary of Final Rule: We are modifying the existing sale of practice safe harbor to protect payments made to a practitioner by a hospital or other entity to purchase the practitioner's practice where the following conditions are satisfied:

- The sale is completed within 3 years.
- After completion of the sale, the practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing entity for which payment may be made by a Federal health care program.
- The practice being acquired must be located in a HPSA for the practitioner's specialty area.
- Commencing at the time of the sale, the purchasing entity must diligently and in good faith engage in recruitment activities that (i) may reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within 1 year of completion of the sale, and (ii) satisfy the conditions of the new practitioner recruitment safe harbor (§ 1001.952(n)).

Comments and Responses

Comment: Commenters generally supported our proposed modification to the sale of practice safe harbor. Some commenters urged that the safe harbor be extended to sales of practices in urban underserved areas. One commenter stated that the problem of preserving and maintaining a retiring physician's practice until a new physician can be recruited and established exists in both urban and rural HPSAs. Because of these difficulties, a hospital may find itself in the position of ''holding'' a practice for some time. One commenter suggested that in the case of small, rural hospitals with tight cash flow, the payment period under the safe harbor should be 3 to 5 years, rather than 1 year as set forth in the existing safe harbor.

Several commenters stated that the existing sale of practice safe harbor is too narrow. Some commenters suggested that the safe harbor be expanded to include entities other than hospitals, such as hospital systems and other health care organizations. These commenters urged the OIG to modify the safe harbor to protect, among other arrangements, sales of practices in accordance with fair market value transactions and sales of practices to entities in connection with the process of creating integrated health care delivery systems. One commenter urged the OIG to modify the safe harbor to provide that reasonable valuation of all assets, tangible and intangible, may be used to determine the market value of the practice.

Response: Based on the comments we received to our solicitation and after further consideration, we are persuaded that a need exists to protect certain practice acquisitions by hospitals and other entities located in rural and urban underserved areas that are engaged in practitioner recruitment programs, and that these arrangements can be protected without concurrently immunizing potentially fraudulent or abusive practices. Specifically, we are modifying the sale of practice safe harbor to protect acquisitions of the practices of physicians in underserved areas who are retiring or relocating a distance that would preclude them from being in a position to make referrals to the purchasing entity, if the acquisitions occur as part of a practitioner recruitment program that qualifies for protection under the safe harbor for practitioner recruitment contained in these regulations. We are requiring that the physician be retired from the practice of medicine or otherwise no longer in a position to generate referrals for the hospital. A purchase of a practice from a physician potentially still in a position to make referrals to the purchasing entity might result in abusive payments to induce referrals of business from the physician's new practice. Relocation a significant distance from the practice being sold is an indicator that a physician is no longer in a position to refer patients. We agree that a longer payment period is appropriate in the context of this safe harbor; accordingly, we are establishing a 3 year period for completion of the sale from the date of the first agreement pertaining to the sale.

As a result, to be protected, a sale of practice by a practitioner must meet all of the following conditions: (1) The period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than 3 years; (2) following the sale, the practitioner may not be in a position to make or influence referrals to, or otherwise generate business for, the purchasing entity for which payment may be made in whole or in part under a Federal health care program; (3) the practice being acquired must be located in a HPSA for the practitioner's specialty area; (4) commencing at the time of the first agreement pertaining to the sale, the purchasing entity must diligently and in good faith engage in commercially reasonable recruitment activities that (i) may reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within a 1 year period, and (ii) will satisfy the conditions of the practitioner recruitment safe harbor at § 1001.952(n).

We are not inclined at this time to modify the sale of practice safe harbor further. While we do not intend to stand in the way of integrated delivery system acquisitions of practices, we are concerned that many such arrangements may provide incentives for overutilization, increased billings to the Federal programs, and inappropriate steering of patients in circumstances where the Federal health care programs pay on a fee-for-service basis. Moreover, we remain of the opinion that payments for ''intangibles'' can easily be used to disguise payments for referrals of Federal health care program business, and therefore we are unwilling to provide safe harbor protection for any particular valuation methodology.

III. Regulatory Impact Statement

Executive Order 12866, the Unfunded Mandates Reform Act and Regulatory Flexibility Act

The Office of Management and Budget has reviewed this final rule in accordance with the provisions of Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and has determined that it does not meet the criteria for an economically significant regulatory action. Executive Order 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety distributive and equity effects). The Unfunded Mandates Reform Act, Public Law 104–4, requires that agencies prepare an assessment of anticipated costs and benefits on any rulemaking that may result in an annual expenditure by State, local or tribal government, or by the private sector of $100 million or more. In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small businesses, the Secretary must specifically consider the economic effect of a rule on small business entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity and available information. Regulations must meet certain standards, such as avoiding unnecessary

burden. We believe that this final rule should have no significant economic impact. The safe harbor provisions set forth in this rulemaking are designed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy. In doing so, these regulations impose no requirements on any party. Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement actions under the anti-kickback statute.

We believe that any aggregate economic effect of these safe harbor regulations will be minimal and will impact only those limited few who engage in prohibited behavior in violation of the statute. As such, we believe that the aggregate economic impact of these regulations is minimal and will have no effect on the economy or on Federal or State expenditures.

Additionally, in accordance with the Unfunded Mandates Reform Act of 1995, we have determined that there are no significant costs associated with these safe harbor guidelines that would impose any mandates on State, local or tribal governments, or the private sector that will result in an annual expenditure of $100 million or more, and that a full analysis under the Act is not necessary.

Further, in accordance with the Regulatory Flexibility Act (RFA) of 1980, and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, we are required to determine if this rule will have a significant economic effect on a substantial number of small entities and, if so, to identify regulatory options that could lessen the impact. While some of these safe harbor provisions may have an impact on small entities, we believe that the aggregate economic impact of this rulemaking should be minimal, since it is the nature of the violation and not the size of the entity that will result in a violation of the anti-kickback statute. Since the vast majority of individuals and entities potentially affected by these regulations do not engage in prohibited arrangements, schemes or practices in violation of the law, we have concluded that these final regulations should not have a significant economic impact on a number of small business entities, and that a regulatory flexibility analysis is not required for this rulemaking.

Paperwork Reduction Act

As indicated above, the provisions of these final regulations are voluntary and impose no new reporting or recordkeeping requirements on health care providers necessitating clearance by OMB.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare.

Accordingly, 42 CFR part 1001 is amended as set forth below:

PART 1001—[AMENDED]

1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2) (D), (E) and (F), and 1395hh; and sec. 2455, Pub.L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

2. Section 1001.952 is amended as follows:

a. By republishing the introductory text;

b. Revising paragraph (a), introductory text;

c. Republishing paragraph (a)(1), introductory text;

d. Revising paragraphs (a)(1)(ii) and (iv), (a)(2)(i), (vi) and (vii);

e. Adding a new paragraph (a)(3)

f. Redesignating the closing definitional paragraph in paragraph (a); as paragraph (a)(4) and revising it;

g. Revising paragraph (b), and introductory text, and paragraph (b)(2) and adding a new paragraph (b)(6);

h. Revising paragraph (c), and introductory text, and paragraph (c)(2) and adding a new paragraph (c)(6);

i. Revising paragraph (d), introductory text, and paragraph (d)(2) and adding a new paragraph (d)(7);

j. Revising paragraph (e);

k. Republishing paragraph (f), introductory text, and revising paragraph (f)(2);

l. Revising paragraph (h); and

m. Adding new paragraphs (n) through (s).

The additions and revisions to § 1001.952 read as follows:

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

(a) *Investment interests.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as all of the applicable standards are met within one of the following three categories of entities:

(1) If, within the previous fiscal year or previous 12 month period, the entity possesses more than $50,000,000 in undepreciated net tangible assets (based on the net acquisition cost of purchasing such assets from an unrelated entity) related to the furnishing of health care items and services, all of the following five standards must be met—

* * * * *

(ii) The investment interest of an investor in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be obtained on terms (including any direct or indirect transferability restrictions) and at a price equally available to the public when trading on a registered securities exchange, such as the New York Stock Exchange or the American Stock Exchange, or in accordance with the National Association of Securities Dealers Automated Quotation System.

* * * * *

(iv) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

* * * * *

(2) * * *

(i) No more than 40 percent of the value of the investment interests of each class of investment interests may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. (For purposes of paragraph (a)(2)(i) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.)

* * * * *

(vi) No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors.

(vii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the

entity if the investor uses any part of such loan to obtain the investment interest.

* * * * *

(3)(i) If the entity possesses investment interests that are held by either active or passive investors and is located in an underserved area, all of the following eight standards must be met—

(A) No more than 50 percent of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous 12-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity. (For purposes of paragraph (a)(3)(i)(A) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.)

(B) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(C) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(D) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(E) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross-referral agreement) to passive investors differently than to non-investors.

(F) At least 75 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period must be derived from the service of persons who reside in an underserved area or are members of medically underserved populations.

(G) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(H) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(ii) If an entity that otherwise meets all of the above standards is located in an area that was an underserved area at the time of the initial investment, but subsequently ceases to be an underserved area, the entity will be deemed to comply with paragraph (a)(3)(i) of this section for a period equal to the lesser of:

(A) The current term of the investment remaining after the date upon which the area ceased to be an underserved area or

(B) Three years from the date the area ceased to be an underserved area.

(4) For purposes of paragraph (a) of this section, the following terms apply. *Active investor* means an investor either who is responsible for the day-to-day management of the entity and is a bona fide general partner in a partnership under the Uniform Partnership Act or who agrees in writing to undertake liability for the actions of the entity's agents acting within the scope of their agency. *Investment interest* means a security issued by an entity, and may include the following classes of investments: shares in a corporation, interests or units in a partnership or limited liability company, bonds, debentures, notes, or other debt instruments. *Investor* means an individual or entity either who directly holds an investment interest in an entity, or who holds such investment interest indirectly by, including but not limited to, such means as having a family member hold such investment interest or holding a legal or beneficial interest in another entity (such as a trust or holding company) that holds such investment interest. *Passive investor* means an investor who is not an active investor, such as a limited partner in a partnership under the Uniform Partnership Act, a shareholder in a corporation, or a holder of a debt security. *Underserved area* means any defined geographic area that is designated as a Medically Underserved Area (MUA) in accordance with regulations issued by the Department. *Medically underserved population* means a Medically Underserved Population (MUP) in accordance with regulations issued by the Department.

(b) *Space rental.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following six standards are met—

* * * * *

(2) The lease covers all of the premises leased between the parties for the term of the lease and specifies the premises covered by the lease.

* * * * *

(6) The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

* * * * *

(c) *Equipment rental.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following six standards are met—

* * * * *

(2) The lease covers all of the equipment leased between the parties for the term of the lease and specifies the equipment covered by the lease.

* * * * *

(6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

* * * * *

(d) *Personal services and management contracts.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met—

* * * * *

(2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

* * * * *

(7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

* * * * *

(e) *Sale of practice.* (1) As used in section 1128B of the Act, ''remuneration'' does not include any payment made to a practitioner by another practitioner where the former practitioner is selling his or her practice to the latter practitioner, as long as both of the following two standards are met—

(i) The period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than one year.

(ii) The practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in part under Medicare or a State health care program after one year from the date of the first agreement pertaining to the sale.

(2) As used in section 1128B of the Act, ''remuneration'' does not include any payment made to a practitioner by a hospital or other entity where the practitioner is selling his or her practice to the hospital or other entity, so long as the following four standards are met:

(i) The period from the date of the first agreement pertaining to the sale to the completion date of the sale is not more than three years.

(ii) The practitioner who is selling his or her practice will not be in a professional position after completion of the sale to make or influence referrals to, or otherwise generate business for, the purchasing hospital or entity for which payment may be made in whole or in part under Medicare or a State health care program.

(iii) The practice being acquired must be located in a Health Professional Shortage Area (HPSA), as defined in Departmental regulations, for the practitioner's specialty area.

(iv) Commencing at the time of the first agreement pertaining to the sale, the purchasing hospital or entity must diligently and in good faith engage in commercially reasonable recruitment activities that:

(A) May reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within a one year period and

(B) Will satisfy the conditions of the practitioner recruitment safe harbor in accordance with paragraph (n) of this section.

(f) *Referral services.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value between an individual or entity (''participant'') and another entity serving as a referral service (''referral service''), as long as all of the following four standards are met—

* * * * *

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by either party for the other party for which payment may be made in whole or in part under Medicare or a State health care program.

* * * * *

(h) *Discounts.* As used in section 1128B of the Act, ''remuneration'' does not include a discount, as defined in paragraph (h)(5) of this section, on an item or service for which payment may be made, in whole or in part, under Medicare or a State health care program for a *buyer* as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section; a *seller* as long as the seller complies with the applicable standards of paragraph (h)(2) of this section; and an *offeror* of a discount who is not a seller under paragraph (h)(2) of this section so long as such offeror complies with the applicable standards of paragraph (h)(3) of this section:

(1) With respect to the following three categories of buyers, *the buyer must comply with all of the applicable standards within one of the three following categories*—

(i) If the buyer is an entity which is a health maintenance organization (HMO) or a competitive medical plan (CMP) acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, it need not report the discount except as otherwise may be required under the risk contract.

(ii) If the buyer is an entity which reports its costs on a cost report required by the Department or a State health care program, it must comply with all of the following four standards—

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;

(B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(C) The buyer must fully and accurately report the discount in the applicable cost report; and

(D) the buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section, or information provided by the offeror as specified in paragraph (h)(3)(ii) of this section.

(iii) If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare or a State health care program (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the buyer must comply with both of the following standards—

(A) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and

(B) the buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(iii)(B) of this section, or information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section.

(2) The seller is an individual or entity that supplies an item or service for which payment may be made, in whole or in part, under Medicare or a State health care program to the buyer and who permits a discount to be taken off the buyer's purchase price. The seller must comply with all of the applicable standards within the following three categories—

(i) If the buyer is an entity which is an HMO a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the seller must comply with either of the following two standards—

(A) Where a discount is required to be reported to Medicare or a State health care program under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph; or

(B) Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; when the value of the discount becomes

known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and refrain from doing anything which would impede the buyer from meeting its obligations under this paragraph.

(iii) If the buyer is an individual or entity not included in paragraph (h)(2)(i) or (h)(2)(ii) of this section, the seller must comply with either of the following two standards—

(A) Where the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed, the seller must provide, upon request by the Secretary or a State agency, information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section; or

(B) Where the buyer submits a claim, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.

(3) The offeror of a discount is an individual or entity who is not a seller under paragraph (h)(2) of this section, but promotes the purchase of an item or service by a buyer under paragraph (h)(1) of this section at a reduced price for which payment may be made, in whole or in part, under Medicare or a State health care program. The offeror must comply with all of the applicable standards within the following three categories—

(i) If the buyer is an entity which is an HMO or a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the offeror need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the offeror must comply with the following two standards—

(A) The offeror must inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such a discount and to provide information upon request under paragraph (h)(1) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's ability to meet its obligations under this paragraph.

(iii) If the buyer is an individual or entity in whose name a request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare or a State health care program (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the offeror must comply with the following two standards—

(A) The offeror must inform the individual or entity submitting the claim or request for payment in a manner reasonably calculated to give notice to the individual or entity of its obligations to report such a discount and to provide information upon request under paragraphs (h)(1) and (h)(2) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's or seller's ability to meet its obligations under this paragraph.

(4) For purposes of this paragraph, a *rebate* is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.

(5) For purposes of this paragraph, the term *discount* means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction. The term *discount* does not include—

(i) Cash payment or cash equivalents (except that rebates as defined in paragraph (h)(4) of this section may be in the form of a check);

(ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;

(iii) A reduction in price applicable to one payer but not to Medicare or a State health care program;

(iv) A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;

(v) Warranties;

(vi) Services provided in accordance with a personal or management services contract; or

(vii) Other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section.

(n) *Practitioner recruitment.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value by an entity in order to induce a practitioner who has been practicing within his or her current specialty for less than one year to locate, or to induce any other practitioner to relocate, his or her primary place of practice into a HPSA for his or her specialty area, as defined in Departmental regulations, that is served by the entity, as long as all of the following nine standards are met—

(1) The arrangement is set forth in a written agreement signed by the parties that specifies the benefits provided by the entity, the terms under which the benefits are to be provided, and the obligations of each party.

(2) If a practitioner is leaving an established practice, at least 75 percent of the revenues of the new practice must be generated from new patients not previously seen by the practitioner at his or her former practice.

(3) The benefits are provided by the entity for a period not in excess of 3 years, and the terms of the agreement are not renegotiated during this 3-year period in any substantial aspect; provided, however, that if the HPSA to which the practitioner was recruited ceases to be a HPSA during the term of the written agreement, the payments made under the written agreement will continue to satisfy this paragraph for the duration of the written agreement (not to exceed 3 years).

(4) There is no requirement that the practitioner make referrals to, be in a position to make or influence referrals to, or otherwise generate business for the entity as a condition for receiving the benefits; provided, however, that for purposes of this paragraph, the entity may require as a condition for receiving benefits that the practitioner maintain staff privileges at the entity.

(5) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

(6) The amount or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare or a State health care program.

(7) The practitioner agrees to treat patients receiving medical benefits or assistance under any Federal health care

program in a nondiscriminatory manner.

(8) At least 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA or a Medically Underserved Area (MUA) or who are part of a Medically Underserved Population (MUP), all as defined in paragraph (a) of this section.

(9) The payment or exchange of anything of value may not directly or indirectly benefit any person (other than the practitioner being recruited) or entity in a position to make or influence referrals to the entity providing the recruitment payments or benefits of items or services payable by a Federal health care program.

(o) *Obstetrical malpractice insurance subsidies.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a hospital or other entity to another entity that is providing malpractice insurance (including a self-funded entity), where such payment is used to pay for some or all of the costs of malpractice insurance premiums for a practitioner (including a certified nurse-midwife as defined in section 1861(gg) of the Act) who engages in obstetrical practice as a routine part of his or her medical practice in a primary care HPSA, as long as all of the following seven standards are met—

(1) The payment is made in accordance with a written agreement between the entity paying the premiums and the practitioner, which sets out the payments to be made by the entity, and the terms under which the payments are to be provided.

(2)(i) The practitioner must certify that for the initial coverage period (not to exceed one year) the practitioner has a reasonable basis for believing that at least 75 percent of the practitioner's obstetrical patients treated under the coverage of the malpractice insurance will either—

(A) Reside in a HPSA or MUA, as defined in paragraph (a) of this section; or

(B) Be part of a MUP, as defined in paragraph (a) of this section.

(ii) Thereafter, for each additional coverage period (not to exceed one year), at least 75 percent of the practitioner's obstetrical patients treated under the prior coverage period (not to exceed one year) must have—

(A) Resided in a HPSA or MUA, as defined in paragraph (a) of this section; or

(B) Been part of a MUP, as defined in paragraph (a) of this section.

(3) There is no requirement that the practitioner make referrals to, or otherwise generate business for, the entity as a condition for receiving the benefits.

(4) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

(5) The amount of payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare or a State health care program.

(6) The practitioner must treat obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(7) The insurance is a bona fide malpractice insurance policy or program, and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance. For purposes of paragraph (o) of this section, *costs of malpractice insurance premiums* means:

(i) For practitioners who engage in obstetrical practice full-time, any costs attributable to malpractice insurance; or

(ii) For practitioners who engage in obstetrical practice on a part-time or sporadic basis, the costs:

(A) Attributable exclusively to the obstetrical portion of the practitioner's malpractice insurance and

(B) Related exclusively to obstetrical services provided in a primary care HPSA.

(p) *Investments in group practices.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to a solo or group practitioner investing in his or her own practice or group practice if the following four standards are met—

(1) The equity interests in the practice or group must be held by licensed health care professionals who practice in the practice or group.

(2) The equity interests must be in the practice or group itself, and not some subdivision of the practice or group.

(3) In the case of group practices, the practice must:

(i) Meet the definition of ''group practice'' in section 1877(h)(4) of the Social Security Act and implementing regulations; and

(ii) Be a unified business with centralized decision-making, pooling of expenses and revenues, and a compensation/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers.

(4) Revenues from ancillary services, if any, must be derived from ''in-office ancillary services'' that meet the definition of such term in section 1877(b)(2) of the Act and implementing regulations.

(q) *Cooperative hospital service organizations.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made between a cooperative hospital service organization (CHSO) and its patron-hospital, both of which are described in section 501(e) of the Internal Revenue Code of 1986 and are tax-exempt under section 501(c)(3) of the Internal Revenue Code, where the CHSO is wholly owned by two or more patron-hospitals, as long as the following standards are met—

(1) If the patron-hospital makes a payment to the CHSO, the payment must be for the purpose of paying for the bona fide operating expenses of the CHSO, or

(2) If the CHSO makes a payment to the patron-hospital, the payment must be for the purpose of paying a distribution of net earnings required to be made under section 501(e)(2) of the Internal Revenue Code of 1986.

(r) *Ambulatory surgical centers.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor, as long as the investment entity is a certified ambulatory surgical center (ASC) under part 416 of this title, whose operating and recovery room space is dedicated exclusively to the ASC, patients referred to the investment entity by an investor are fully informed of the investor's investment interest, and all of the applicable standards are met within one of the following four categories—

(1) *Surgeon-owned ASCs*—If all of the investors are general surgeons or surgeons engaged in the same surgical specialty, who are in a position to refer patients directly to the entity and perform surgery on such referred patients; surgical group practices (as defined in this paragraph) composed exclusively of such surgeons; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or

expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each surgeon investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures (as defined in this paragraph).

(iii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(v) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vi) The entity and any surgeon investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(2) *Single-Specialty ASCs*—If all of the investors are physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices (as defined in this paragraph) composed exclusively of such physicians; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures (as defined in this paragraph).

(iii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(v) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vi) The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(3) *Multi-Specialty ASCs*—If all of the investors are physicians who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices, as defined in this paragraph, composed exclusively of such physicians; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following seven standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures (as defined in this paragraph).

(iii) At least one-third of the procedures (as defined in this paragraph) performed by each physician investor for the previous fiscal year or previous 12-month period must be performed at the investment entity.

(iv) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(vi) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vii) The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(4) *Hospital/Physician ASCs*—If at least one investor is a hospital, and all of the remaining investors are physicians who meet the requirements of paragraphs (r)(1), (r)(2) or (r)(3) of this section; group practices (as defined in this paragraph) composed of such physicians; surgical group practices (as defined in this paragraph); or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to refer patients directly or indirectly to the entity or any of its investors, all of the following eight standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iii) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(iv) The entity and any hospital or physician investor must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(v) The entity may not use space, including, but not limited to, operating and recovery room space, located in or owned by any hospital investor, unless

such space is leased from the hospital in accordance with a lease that complies with all the standards of the space rental safe harbor set forth in paragraph (b) of this section; nor may it use equipment owned by or services provided by the hospital unless such equipment is leased in accordance with a lease that complies with the equipment rental safe harbor set forth in paragraph (c) of this section, and such services are provided in accordance with a contract that complies with the personal services and management contracts safe harbor set forth in paragraph (d) of this section.

(vi) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vii) The hospital may not include on its cost report or any claim for payment from a Federal health care program any costs associated with the ASC (unless such costs are required to be included by a Federal health care program).

(viii) The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity.

(5) For purposes of paragraph (r) of this section, *procedures* means any procedure or procedures on the list of Medicare-covered procedures for ambulatory surgical centers in accordance with regulations issued by the Department and *group practice* means a group practice that meets all of the standards of paragraph (p) of this section. *Surgical group practice* means a group practice that meets all of the standards of paragraph (p) of this section and is composed exclusively of surgeons who meet the requirements of paragraph (r)(1) of this section.

(s) *Referral agreements for specialty services.* As used in section 1128B of the Act, *remuneration* does not include any exchange of value among individuals and entities where one party agrees to refer a patient to the other party for the provision of a specialty service payable in whole or in part under Medicare or a State health care program in return for an agreement on the part of the other party to refer that patient back at a mutually agreed upon time or circumstance as long as the following four standards are met—

(1) The mutually agreed upon time or circumstance for referring the patient back to the originating individual or entity is clinically appropriate.

(2) The service for which the referral is made is not within the medical expertise of the referring individual or entity, but is within the special expertise of the other party receiving the referral.

(3) The parties receive no payment from each other for the referral and do not share or split a global fee from any Federal health care program in connection with the referred patient.

(4) Unless both parties belong to the same group practice as defined in paragraph (p) of this section, the only exchange of value between the parties is the remuneration the parties receive directly from third-party payors or the patient compensating the parties for the services they each have furnished to the patient.

Dated: February 4, 1999.

June Gibbs Brown,

Inspector General.

Approved: June 9, 1999.

Donna E. Shalala,

Secretary.

[FR Doc. 99–29989 Filed 11–18–99; 8:45 am]

BILLING CODE 4150–04–P

Friday
November 19, 1999

Part VI

Department of Agriculture

Solicitation of Input From Stakeholders Regarding the Integrated Research, Education, and Extension Competitive Grants Program; Public Meeting and Delegation of Authority; Notice

DEPARTMENT OF AGRICULTURE

Solicitation of Input From Stakeholders Regarding the Integrated Research, Education, and Extension Competitive Grants Program; Public Meeting and Delegation of Authority

AGENCY: Office of the Secretary, Department of Agriculture (USDA).

ACTION: Notice of public meeting and delegation of authority.

SUMMARY: The Cooperative State Research, Education, and Extension Service (CSREES) is creating a new research, education, and extension program called the Integrated Research, Education, and Extension Competitive Grants Program. By this notice, CSREES is designated to act on behalf of the Secretary of Agriculture in soliciting public comment from persons who use or conduct research, extension, or education regarding the priorities to be addressed by this new program as required under section 102(a) and (b) of the Agricultural Research, Extension, and Education Reform Act of 1998 (AREERA).

DATES: The meeting will be held on Thursday, December 2, 1999, from 9:00 a.m. to 4:00 p.m. Because of the diversity of subjects, and to aid participants in scheduling their attendance, the following schedule is anticipated:

9:00–9:30 a.m.—Introduction to Section 406
9:30–10:45 a.m.—Water Quality
10:45–12:00 p.m.—Food Safety
1:00–2:30 p.m.—Pest Management (Pesticide Impact Assessment, FQPA, and Methyl Bromide)
2:30–4:00 p.m.—Other Issues Pertaining to 406 Priorities and Administration

ADDRESSES: The meeting will be held in room 107A, Jamie L. Whitten Federal Building, United States Department of Agriculture, 12th and Jefferson Drive, SW, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Persons wishing to present oral comments at this meeting are requested to pre-register by contacting Ms. Terri Joya at (202) 401–1761, by fax at (202) 401–1782 or by e-mail to tjoya@reeusda.gov. Participants may reserve a 5-minute comment period and should indicate the topic area for which they are registering. More time may be available, depending on the number of people wishing to make a presentation and the time needed for questions, following the presentation. Reservations will be confirmed on a first-come, first-served basis. All other attendees may register at the meeting. Written comments may also be submitted for the record at the meeting or mailed to Ms. Terri Joya, Competitive Research Grants and Awards Management, USDA/CSREES, STOP 2240, 1400 Independence Avenue, SW, Washington, DC 20250–2240. Please provide three copies of the comments. All comments must be received by Friday, December 17, 1999, to be considered. All comments and the official transcript of the meeting, when it becomes available, will be available for review for six months on the CSREES web page. Participants who require a sign language interpreter or other special accommodations should contact Ms. Joya as directed above.

SUPPLEMENTARY INFORMATION:

Background and Purpose

Section 406 of AREERA (7 U.S.C. 7626) authorized the Secretary of Agriculture to establish a research, education, and extension competitive grant program to provide funding for integrated, multifunctional agricultural research, extension, and education activities. Subject to the availability of appropriations to carry out this program, the Secretary may award grants to colleges and universities (as defined in section 1404 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3103)) on a competitive basis for integrated research, education, and extension projects. Grants shall be awarded to address priorities in United States agriculture that involve integrated research, education, and extension activities as determined by the Secretary in consultation with the National Agricultural Research, Extension, Education, and Economics Advisory Board. The Secretary delegates the authority to carry out this program to CSREES.

CSREES is holding a public meeting to obtain comments to use in developing the proposed rule for the new Integrated Research, Education, and Extension Competitive Grants Program. The meeting is open to the public. Written comments and suggestions on issues that may be considered in the meeting may be submitted to the CSREES Docket Clerk at the address above.

Summary of Integrated Activities

The Program will be funded in fiscal year (FY) 2000 at $39,541,000 for the following integrated activities: Water Quality ($13 million), Food Safety ($15 million), Pesticide Impact Assessment ($4.541 million), Crops at Risk from Food Quality and Protection Act (FQPA) Implementation ($1 million), FQPA Risk Mitigation Program for Major Food Crop Systems ($4 million), and Methyl Bromide Transition Program ($2 million).

Listed below is subject area information about integrated activities that USDA may fund in FY 2000:

Water Quality—This program is targeted to the identification and resolution of agriculturally-related water quality degradation and seeks the development of partnerships to generate and educate on best watershed practices.

Food Safety—This program provides information for research, education, and extension to improve the safety of food products and to create a public that is more informed about food safety issues.

Pesticide Impact Assessment—This program provides for the most objective and accurate data collection program on FQPA issues which is provided to USDA and the Environmental Protection Agency (EPA) to allow for more informed regulatory decision making.

Crops at Risk from FQPA Implementation—This program is an intermediate-term research and extension program with at-risk cropping system as the focal point. Development of new multiple-tactic Integrated Pest Management (IPM) strategies designed to assist in the transition period for certain pesticides affected by the implementation of the FQPA is a potential goal of the program.

FQPA Risk Mitigation Program for Major Food Crop Systems—This program will emphasize development and implementation of new and innovative pest management systems designed to maintain the productivity and profitability of major acreage crops while meeting or exceeding environmental quality and human health standards as the FQPA is implemented.

Methyl Bromide Transitions Program—This program is designed to support the discovery and implementation of practical pest management alternatives for commodities affected by the methyl bromide phase-out. The program will focus on short- to medium-term solutions for commodities at risk using either combinations of presently available technologies or some newly developed practices.

Done at Washington, DC, this 16 day of November 1999.

Dan Glickman,

Secretary, Department of Agriculture.

[FR Doc. 99–30400 Filed 11–17–99; 4:04 pm]

BILLING CODE 3410–22–P

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The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at http://www.access.gpo.gov/nara/index.html. Some laws may not yet be available.

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Nursing Relief for Disadvantaged Areas Act of 1999 (Nov. 12, 1999; 113 Stat. 1312)

H.R. 609/P.L. 106–96

To amend the Export Apple and Pear Act to limit the applicability of the Act to apples. (Nov. 12, 1999; 113 Stat. 1321)

H.R. 915/P.L. 106–97

To authorize a cost of living adjustment in the pay of administrative law judges. (Nov. 12, 1999; 113 Stat. 1322)

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H.R. 3122/P.L. 106–100

To permit the enrollment in the House of Representatives Child Care Center of children of Federal employees who are not employees of the legislative branch. (Nov. 12, 1999; 113 Stat. 1332)

H.J. Res. 54/P.L. 106–101

Granting the consent of Congress to the Missouri-Nebraska Boundary Compact. (Nov. 12, 1999; 113 Stat. 1333)

S. 900/P.L. 106–102

Gramm-Leach-Bliley Act (Nov. 12, 1999; 113 Stat. 1338)

H.R. 348/P.L. 106–103

To authorize the construction of a monument to honor those who have served the Nation's civil defense and emergency management programs. (Nov. 13, 1999; 113 Stat. 1482)

H.R. 3061/P.L. 106–104

To amend the Immigration and Nationality Act to extend for an additional 2 years the period for admission of an alien as a nonimmigrant under section 101(a)(15)(S) of such Act, and to authorize appropriations for the refugee assistance program under chapter 2 of title IV of the Immigration and Nationality Act. (Nov. 13, 1999; 113 Stat. 1483)

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