

we are revoking the requirements in § 890.5290(b) related to the classification of SWT as class III devices and codifying the reclassification of SWT into class II (special controls).

VIII. Reference

FDA has placed the following reference on display in the Division of Dockets Management (HFA-305) Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Interested persons may see it between 9 a.m. and 4 p.m., Monday through Friday, and online at <http://www.regulations.gov>.

1. FDA's Orthopedic and Rehabilitation Devices Panel transcript and other meeting materials are available on FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm352525.htm>.

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 890.5290 is amended by revising paragraphs (a)(1) and (b) and removing paragraph (c).

The revisions read as follows:

§ 890.5290 Shortwave diathermy.

(a) *Shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions—(1) Identification.* A shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the radiofrequency (RF) bands of 13.56 megahertz (MHz) or 27.12 MHz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

* * * * *

(b) *Nonthermal shortwave therapy—(1) Identification.* A nonthermal

shortwave therapy is a prescription device that applies to the body pulsed electromagnetic energy in the RF bands of 13.56 MHz or 27.12 MHz and that is intended for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

(2) *Classification: Class II (special controls).* The device is classified as class II. The special controls for this device are:

(i) Components of the device that come into human contact must be demonstrated to be biocompatible.

(ii) Appropriate analysis/testing must demonstrate that the device is electrically safe and electromagnetically compatible in its intended use environment.

(iii) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Non-clinical performance testing must characterize the output waveform of the device and demonstrate that the device meets appropriate output performance specifications. The output characteristics and the methods used to determine these characteristics, including the following, must be determined:

- (A) Peak output power;
- (B) Pulse width;
- (C) Pulse frequency;
- (D) Duty cycle;
- (E) Characteristics of other types of modulation that may be used;
- (F) Average measured output powered into the RF antenna/applicator;
- (G) Specific absorption rates in saline gel test load or other appropriate model;
- (H) Characterization of the electrical and magnetic fields in saline gel test load or other appropriate model for each RF antenna and prescribed RF antenna orientation/position; and
- (I) Characterization of the deposited energy density in saline gel test load or other appropriate model.

(iv) A detailed summary of the clinical testing pertinent to use of the device to demonstrate the effectiveness of the device in its intended use.

(v) Labeling must include the following:

- (A) Output characteristics of the device;
- (B) Recommended treatment regimes, including duration of use; and
- (C) A detailed summary of the clinical testing pertinent to the use of the device and a summary of the adverse events and complications.

(vi) Nonthermal shortwave therapy devices marketed prior to the effective

date of this reclassification must submit an amendment to their previously cleared premarket notification (510(k)) demonstrating compliance with these special controls.

Dated: October 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 625

[Docket No. FHWA-2015-0003]

RIN 2125-AF67

Design Standards for Highways

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This rule updates the regulations governing the required design standards to be utilized on Federal-aid highway program (FAHP) projects. In issuing the final rule, FHWA incorporates by reference the latest versions of design standards and standard specifications previously adopted and incorporated by reference, and removes the corresponding outdated or superseded versions of these standards and specifications. This rule also makes technical changes to the regulatory text consistent with updated **Federal Register** procedures.

DATES: This final rule is effective November 12, 2015. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of November 12, 2015.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Matzke, Office of Program Administration (HIPA-20), (202) 366-4658, or via email at michael.matzke@dot.gov, or Mr. Robert Black, Office of the Chief Counsel (HCC-30), (202) 366-1373, or via email at robert.black@dot.gov. Office hours are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document, the notice of proposed rulemaking (NPRM), and all comments received may be viewed online through the Federal eRulemaking portal at: <http://www.regulations.gov>. The Web site is available 24 hours each

day, 365 days each year. Please follow the instructions. An electronic copy of this document may also be downloaded by accessing the Office of Federal Register's home page at: <http://www.archives.gov/federal-register/>, or the Government Printing Office's Web page at: <http://www.gpo.gov/fdsys>.

Background

This rulemaking updates existing regulations governing new construction, reconstruction, resurfacing (except for maintenance resurfacing), restoration, and rehabilitation projects on the National Highway System (NHS), including the Interstate System, by incorporating by reference the current versions of design standards and standard specifications previously adopted and incorporated by reference under 23 CFR 625.4, and removing the outdated or superseded versions of these standards and specifications. Several of these design standards and standard specifications were established by the American Association of State Highway and Transportation Officials (AASHTO) and the American Welding Society (AWS) and were previously adopted by FHWA through rulemaking. The updated standards or specifications replace previous versions of these documents and represent the most recent refinements that professional organizations have formally accepted. The FHWA formally adopts them for NHS projects.

The revisions include referencing the 2011 edition of the AASHTO *A Policy on Geometric Design of Highways and Streets*, commonly referred to as the Green Book. The revisions also include referencing the current version of AASHTO's Load and Resistance Factor Design (LRFD) Bridge Design Specifications; LRFD Movable Highway Bridge Design Specifications; and Standard Specifications for Structural Supports of Highway Signs, Luminaires and Traffic Signals. In addition, the revisions reference the current version of the AWS Bridge Welding Code and the Structural Welding Code—Reinforcing Steel.

The AASHTO is an organization that represents 52 State transportation agencies (STA) (including the District of Columbia and Puerto Rico). Its members consist of the duly constituted heads and other chief officials of those agencies. The Secretary of Transportation is an ex-officio member, and DOT staff participates in various AASHTO activities as nonvoting representatives. Among other functions, AASHTO develops and issues standards, specifications, policies, guides, and related materials for use by

the States for highway projects. Many of the standards, policies, and standard specifications that were approved by FHWA and incorporated into 23 CFR part 625 were developed and issued by AASHTO.

The revisions also include updated versions of welding codes published by AWS. The AWS is a nonprofit organization known for its code and certification procedures, providing industry standards for welding, including in the transportation field. The AWS reports about 66,000 members worldwide and develops updated materials for welding professionals and other interested parties, including those related to bridge welding and structural welding.

While these adopted standards and specifications apply to all projects on the NHS (including the Interstate System), FHWA encourages the use of flexibility and a context-sensitive approach to consider a full range of project and user needs and the impacts to the community and natural and human environment. The STA and local agencies may consider using design exceptions to achieve a design that balances project and user needs, performance, cost, environmental implications, and community values. These adopted design standards provide a range of acceptable values for highway features, and FHWA encourages the use of this flexibility to achieve a design that best suits the desires of the community while satisfying the purpose for the project and needs of its users.

At a minimum, STAs and local agencies should select design values based on an evaluation of the context of the facility, needs of all the various project users, safety, mobility, human and natural environmental impacts, and project costs. For most situations, there is sufficient flexibility within the range of acceptable values to achieve a balanced design. However, when this is not possible, STAs and local agencies may consider designs that deviate from the design standards when warranted based on the project's impact on the environment (natural and built), historical and recreational facilities, and other factors. In instances where design standards for a particular element cannot be attained, a design exception, subject to approval by FHWA, or on behalf of FHWA if an STA has assumed the responsibility through a Stewardship and Oversight agreement, is required for projects on the NHS. Additional information on FHWA's adopted design standards and design exceptions is available electronically at <http://www.fhwa.dot.gov/design/standards> and in FHWA's publication

titled *Mitigation Strategies for Design Exceptions* available at http://safety.fhwa.dot.gov/geometric/pubs/mitigationstrategies/fhwa_sa_07011.pdf.

In addition, FHWA supports using design guides that national organizations develop from peer-reviewed research, or equivalent guides developed in cooperation with State or local officials, when such guides are not in conflict with Federal laws and regulations.

The rule also makes technical changes to the regulatory text consistent with updated **Federal Register** procedures, including updating mailing addresses and including telephone and Web site addresses in 23 CFR 625.4(d) pertaining to the availability of documents incorporated by reference.

Discussion Under 1 CFR Part 51

The documents FHWA is incorporating by reference are reasonably available to interested parties, primarily STAs and local agencies carrying out Federal-aid highway projects. These documents represent the most recent refinements that professional organizations have formally accepted and are currently in use by the transportation industry. The documents are also available for review at the U.S. Department of Transportation's National Transportation Library, the National Archives and Records Administration, or may be obtained from AASHTO or AWS.

The documents incorporated by reference in this final rule are:

(1) *A Policy on Geometric Design of Highways and Streets*, 6th Edition, AASHTO 2011. The AASHTO, 2011 edition incorporates the latest research and current industry practices, with the basic criteria identified for geometric design standards remaining essentially the same. This Policy is a comprehensive manual to assist STAs and local agencies in administrative, planning, and educational efforts pertaining to design formulation. The Policy includes design guidelines for freeways, arterials, collectors, and local roads in both urban and rural locations.

(2) *A Policy on Design Standards Interstate System*, AASHTO, January 2005. This Policy complements *A Policy on Geometric Design of Highways and Streets and Standard Specifications for Highway Bridges*. Topics include design traffic, right-of-way, geometric controls and criteria, cross section elements, interchanges, and bridges and other structures.

(3) *Standard Specifications for Highway Bridges*, 17th Edition, AASHTO, 2002. This document details

the design standards for the maintenance and rehabilitation of older, existing structures. For new bridge designs, it is superseded by the AASHTO LRFD Bridge Design Specifications (see related item).

(4) AASHTO LRFD Bridge Construction Specifications, 3rd Edition, AASHTO 2010, with 2010, 2011, 2012, and 2014 Interim Revisions. This new edition has been revised to be consistent with its companion, the recently updated *AASHTO LRFD Bridge Design Specifications* (see related item). Among the revisions are improved testing and acceptance criteria, updated material references, and recommended guidelines for construction loads.

(5) AASHTO LRFD Bridge Design Specifications, 7th Edition, AASHTO, 2014, with 2015 Interim Revisions. The *AASHTO LRFD Bridge Design Specifications* are intended for use in the design, evaluation, and rehabilitation of bridges, and are mandated by the FHWA for use on all bridges using Federal funding. These Specifications employ the LRFD methodology using factors developing from current statistical knowledge of loads and structural performance.

(6) AASHTO LRFD Moveable Highway Bridge Design Specifications, 2nd Edition, AASHTO, 2007, including 2008, 2010, 2011, 2012, 2014, and 2015 Interim Revisions. This guide includes information on design of bridge spans, mechanical systems (motors, hydraulics, etc.), electrical systems, and bridge protection systems. The guidelines also cover seismic analysis and vessel impact analysis. Several types of movable bridges are discussed, including Bascule span, Swing span, and Vertical Lift bridges.

(7) AASHTO/AWS D1.5M/D1.5: 2010 Bridge Welding Code, 6th Edition, AASHTO, 2010, with 2011 and 2012 Interim Revisions. This document covers AASHTO welding requirements for welded highway bridges made from carbon and low-alloy construction steels. Chapters cover design of welded connections, workmanship, technique, procedure and performance qualification, inspection, and stud welding. This document features the latest AASHTO revisions and nondestructive examination requirements, as well as a section providing a "Fracture Control Plan for Nonredundant Bridge Members."

(8) Standards for Structural Supports for Highway Signs, Luminaires and Traffic Signals, 6th Edition, AASHTO, 2013. These Standards are applicable to the structural design of supports for highway signs, luminaires, and traffic signals. The Standards are intended to

serve as a standard and guide for the design, fabrication, and erection of these types of supports.

(9) D1.4/D1.4M: 2011 Structural Welding Code—Reinforcing Steel, 7th Edition, American Welding Society, 2011. This manual covers welding of reinforcing steel in most reinforced concrete applications. It includes sections on allowable stresses, structural details, workmanship requirements, technique, procedure and performance qualification, and inspection.

Summary Discussion of Comments Received in Response to the NPRM

On June 2, 2015, FHWA published an NPRM in the **Federal Register** at 80 FR 31327 soliciting public comments on its proposal to update the existing regulations. The following presents an overview of the comments received to the NPRM. The docket contained comments from 11 different parties including 3 STAs, 4 industry organizations, and 4 individuals. The FHWA appreciates the feedback the commenters provided, carefully reviewed and analyzed all the comments that were submitted, and made revisions to the NPRM to incorporate suggestions where necessary.

Summary of STA Comments

The Pennsylvania DOT was concerned that the NPRM lacked implementation timeframes for the updated standards. As an example, they stated that STAs will need to update standard designs for structural support for overhead signs and traffic signals and estimated that it may take 3 years to accomplish this. Pennsylvania DOT went on to suggest implementation timeframes of 1–2 years for standards 23 CFR 625.4(b)(1), (2), (3), (4), (5), and (6); and 3–4 years for standard 23 CFR 625.4(b)(7).

The FHWA believes that the standards and manuals incorporated by reference under this rulemaking, where not in conflict with standards and manuals under the previous regulation, have been used by STAs for projects on the NHS. This final rule is effective for all NHS projects authorized to proceed with design activities on or after the effective date of this rule. While FHWA will not establish any extended implementation timeframes within the regulation, STAs should work closely with their FHWA division office in implementing the final rule.

Both Oklahoma DOT and California DOT expressed support for the update of the standards, specifications, and text.

The Oklahoma DOT and California DOT support was noted. No change was made to the regulation.

Individual's Comments

An individual commenter advised that the address shown in the NPRM 23 CFR 625.4(d)(2) was incorrect and should be: American Welding Society, 8869 NW 36 Street, #130, Miami, FL 33166–6672.

The FHWA agrees and the final rule was revised accordingly.

The individual also noted that in July 2015, the AASHTO Standard in 23 CFR 625.4(c)(2) (Standard Specifications for Transportation Materials and Methods of Sampling and Testing, parts I and II, AASHTO 1995), was superseded by the latest edition of the manual (Standard Specifications for Transportation Materials and Methods of Sampling and Testing, 35th Edition and AASHTO Provisional Standards, 2015 Edition). Furthermore, the Standard Specifications for Structural Supports for Highway Signs, Luminaires and Traffic Signals, 6th Edition, AASHTO 2013 was superseded by LRFD Specifications for Structural Supports for Highway Signs, Luminaires and Traffic Signals, 1st Edition, AASHTO 2015 in August of 2015.

The timing of the updates for the AASHTO materials and structural support publications did not allow for FHWA to propose the adoption of them in the NPRM. The FHWA will consider adopting these two manuals in a future update to the regulations. No change was made to the final rule.

The individual also recommend several other documents for incorporation by reference including a specification for bridge and parking garage deck overlays and several roadway lighting guides and specifications. Generally, the guides and specifications suggested by the commenter refer to specific roadway materials and appurtenances and are left up to STAs to reference as necessary for projects. No changes were made to the final rule to adopt the additional documents suggested by the commenter.

Another individual commenter suggested that the time period for adopting newer versions of the Green Book can be shortened or eliminated by not including specific edition information in the regulation, and that by doing so, FHWA could avoid a formal rulemaking process and adopt newer editions of the Green Book by only issuing a memo or policy paper.

Procedures and requirements for incorporation by reference are covered in 1 CFR part 51. This regulation requires that the language incorporating

a publication by reference be precise and complete and must clearly state the title, date, edition, author, publisher and identification number of the publication. Therefore, no change was made to the final rule.

An individual expressed support for the update as long as it eliminates outdated options for road and road-related infrastructure. A review of the list of outdated options provided by the commenter showed that they mainly related to signing and striping issues and therefore fall under the purview of the Manual on Uniform Traffic Control Devices, or are based on specific design decisions that are made on a project-by-project basis by STAs and local agencies. No change was made to the final rule.

An individual commented that the regulation needs to contain timeline limits for highway projects and that it must require that more time is spent on drainage design since rework after completion of construction can be costly. In addition, the individual suggested that all cloverleaf on and off ramps be replaced to provide for smoother operations on the highway system.

Establishing design and construction schedules and timelines for highway projects is left to STAs and/or local agencies and will depend on many factors such as project complexity, engineering and environmental issues, and agency staffing and resources, to name a few. Similarly, as the owners of the highway system, STAs and/or local agencies are responsible for setting highway improvement priorities according to local needs. As such, it is outside the scope of this rulemaking to set or otherwise require timelines for design and construction of projects. The standards adopted by this regulation address the need for proper drainage design and interchange geometrics, including cloverleaf on and off ramps. No change was made to the final rule.

Industry Organization Comments

The National Association of City Transportation Officials (NACTO), Smart Growth America, and People For Bikes all recommended amending 23 CFR 625 to include the NACTO Urban Street Design Guide¹ and an ITE Recommended Practice/Designing Walkable Urban Thoroughfares: A Context-Sensitive Approach² as design guidance or as standards for urban streets. The NACTO points out that 23 U.S.C. 109(c)(2) requires the Secretary to

consider the publication entitled *Flexibility in Highway Design* and the context-sensitive design approach in the development of design criteria. The NACTO also points out that many city-owned arterial streets were added to the NHS under the Moving Ahead for Progress in the 21st Century Act (Pub. L. 112-141), known as MAP-21, and that a context-sensitive design approach is critical to achieving a balanced design on these roadways. The Smart Growth America and People For Bikes additionally urge FHWA to include; the NACTO Urban Bikeway Design Guide,³ and the FHWA Separated Bike Lane Planning and Design Guide.⁴

Part 625, Design Standards for Highways, contains a listing of documents that define specific criteria and controls for the design of NHS projects. Such documents are referred to as standards. The FHWA and other organizations produce many other documents that serve to complement the design standards. These documents are often referred to as guides, references, or best practices. Non-regulatory information, such as guides and references that serve to complement or supplement design standards need not be included within the Code of Federal Regulations. Instead, FHWA typically recognizes guidance through policy memoranda or development of separate FHWA publications.

As an example, on August 20, 2013, FHWA issued a memorandum⁵ expressing its support for taking a flexible approach to bicycle and pedestrian facility design. The memorandum listed several good resources that can be referenced to develop non-motorized transportation networks, particularly in urban areas. The memorandum references the NACTO *Urban Bikeway Design Guide* and ITE *Designing Walkable Urban Thoroughfares* guide. Subsequent to the date of the memorandum, NACTO published the *Urban Street Design Guide*. The FHWA expressed support for using the new guide in Frequently Asked Questions available on the internet at http://www.fhwa.dot.gov/environment/bicycle_pedestrian/guidance/design_guidance/design_flexibility_qa.cfm.

While adopted standards and specifications apply to all projects on the NHS, the AASHTO Green Book

encourages the use of flexibility and a context-sensitive approach to consider the full range of project and user needs and the impacts to the community and natural and human environment. The 2011 edition, adopted under this rulemaking, strengthens such language and incorporates many of the principles contained in the materials referenced in 23 U.S.C. 109(c)(2). For most situations, there is sufficient flexibility within the range of acceptable values contained in the standards to achieve a balanced design for a variety of roadway classification types. However, when this is not possible, a design exception may be appropriate.

The FHWA does not intend to adopt the guides as standards for the NHS but will continue to recommend the use of a wide array of design resources to achieve context-sensitive urban street designs. Instead, language has been added to the rule to recognize that FHWA supports the use of guides that national organizations develop from peer-reviewed research, or equivalent guides developed in cooperation with State or local officials, when such guides are not in conflict with other Federal laws or regulations.

In addition, FHWA will consider including a similar statement about FHWA support of other guides that serve as supplements to the regulatory standards in future updates to 23 CFR part 652.

The Public Resource.org asserted that the documents to be incorporated by reference into the rule are not reasonably available to the public.

As stated earlier, when proposing to incorporate a document by reference in the regulations, FHWA follows the policies and procedures under 1 CFR part 51 to ensure that the materials proposed to be incorporated are reasonably available to interested parties and usable by the class of persons affected. The NPRM describes where the materials can be obtained by members of the public, including in-person at the Department of Transportation headquarters office. The materials have been formally adopted by professional organizations and have been in use by the community for some time. The FHWA believes these documents to be in use by the STAs and local agencies affected by this rulemaking and thus are reasonably available.

¹ <http://nacto.org/publication/urban-street-design-guide/>.

² <http://www.ite.org/css/online/>.

³ <http://nacto.org/publication/urban-bikeway-design-guide/>.

⁴ http://www.fhwa.dot.gov/environment/bicycle_pedestrian/publications/separated_bikelane_pdg/page00.cfm.

⁵ http://www.fhwa.dot.gov/environment/bicycle_pedestrian/guidance/design_guidance/design_flexibility.cfm.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

The FHWA determined that this action does not constitute a significant regulatory action within the meaning of Executive Order 12866 or within the meaning of DOT regulatory policies and procedures. The amendments update several industry design standards and standard specifications adopted and incorporated by reference under 23 CFR part 625 and remove the corresponding outdated or superseded versions of these standards and specifications. This rule makes technical changes to the regulatory text consistent with updated **Federal Register** procedures.

In addition, this action complies with the principles of Executive Order 13563. After evaluating the costs and benefits of these amendments, FHWA determined that the economic impact of this rulemaking would be minimal. These changes are not anticipated to adversely affect, in any material way, any sector of the economy. In addition, these changes will not create a serious inconsistency with any other agency's action or materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. These updated standards and specifications represent the most recent refinements that professional organizations have formally accepted, and are currently in use by the transportation industry. The FHWA anticipates that the economic impact of this rulemaking will be minimal; therefore, a full regulatory evaluation is not necessary.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), FHWA evaluated the effects of this rule on small entities, such as local governments and businesses. The FHWA determined that this action would not have a significant economic impact on a substantial number of small entities. The amendments would update several industry design standards and standard specifications adopted and incorporated by reference under 23 CFR part 625. The FHWA believes the projected impact upon small entities that utilize Federal-aid highway program funding for the development of highway improvement projects on the NHS would be negligible. Therefore, FHWA certifies that the rule would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This final rule does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). Furthermore, in compliance with the Unfunded Mandates Reform Act of 1995, FHWA evaluated this rule to assess the effects on State, local, and tribal governments and the private sector. This rule does not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$143.1 million or more in any one year (2 U.S.C. 1532). In addition, the definition of “Federal Mandate” in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility.

Executive Order 13132 (Federalism Assessment)

This rule was analyzed in accordance with the principles and criteria contained in Executive Order 13132, dated August 4, 1999, and it was determined that this rule does not have a substantial direct effect or sufficient federalism implications on States that would limit the policymaking discretion of the States. Nothing in this rule directly preempts any State law or regulation or affects the States' ability to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program. This Executive Order applies because State and local governments would be directly affected by the proposed regulation, which is a condition on Federal highway funding. Local entities should refer to the Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction, for further information.

Paperwork Reduction Act

Federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. This rule does not contain a collection of information requirement for the purpose of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

National Environmental Policy Act

The FHWA analyzed this rule for the purposes of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) and determined that this action would not have any effect on the quality of the human and natural environment because it only makes technical changes and incorporates by reference the latest versions of design standards and standard specifications previously adopted and incorporated by reference under 23 CFR part 625 and removes the corresponding outdated or superseded versions of these standards and specifications. The rule qualifies as a categorical exclusion to NEPA under 23 CFR 771.117(c)(20).

Executive Order 13175 (Tribal Consultation)

The FHWA analyzed this rule under Executive Order 13175, dated November 6, 2000, and believes that this action would not have substantial direct effects on one or more Indian tribes, would not impose substantial direct compliance costs on Indian tribal governments, and would not preempt tribal law. This rule establishes the requirements for the procurement, management, and administration of engineering and design related services using FAHP funding and directly related to a construction project. As such, this rule would not impose any direct compliance requirements on Indian tribal governments nor would it have any economic or other impacts on the viability of Indian tribes. Therefore, a tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

The FHWA analyzed this rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. We determined that this action would not be a significant energy action under that order because any action contemplated would not be likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, FHWA certifies that a Statement of Energy Effects under Executive Order 13211 is not required.

Executive Order 12630 (Taking of Private Property)

The FHWA analyzed this rule and determined that this action would not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

The FHWA analyzed this action under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks, and certifies that this proposed action would not cause an environmental risk to health or safety that may disproportionately affect children.

Executive Order 12898 (Environmental Justice)

The Executive Order 12898 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. The FHWA determined that this rule does not raise any environmental justice issues.

Regulation Identifier Number

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 625

Design standards, Grant programs-transportation, Highways and roads, Incorporation by reference.

Issued on: October 6, 2015.

Gregory G. Nadeau,

Administrator, Federal Highway Administration.

In consideration of the foregoing, the FHWA amends 23 CFR part 625 as follows:

PART 625—DESIGN STANDARDS FOR HIGHWAYS

■ 1. The authority citation for part 625 continues to read as follows:

Authority: 23 U.S.C. 109, 215, and 402; Sec. 1073 of Pub. L. 102-240, 105 Stat. 1914, 2012; 49 CFR 1.48(b) and (n).

■ 2. Amend § 625.4 by revising paragraphs (a), (b), and (d), and adding paragraph (e) to read as follows:

§ 625.4 Standards, policies, and standard specifications.

* * * * *

(a) *Roadway and appurtenances.* (1) A Policy on Geometric Design of Highways and Streets, AASHTO, 2011 (incorporated by reference; see § 625.4(d)).

(2) A Policy on Design Standards Interstate System, AASHTO, January 2005 (incorporated by reference; see § 625.4(d)).

(3) The geometric design standards for resurfacing, restoration, and rehabilitation (RRR) projects on NHS highways other than freeways shall be the procedures and the design or design criteria established for individual projects, groups of projects, or all non-freeway RRR projects in a State, and as approved by the FHWA. The other geometric design standards in this section do not apply to RRR projects on NHS highways other than freeways, except as adopted on an individual State basis. The RRR design standards shall reflect the consideration of the traffic, safety, economic, physical, community, and environmental needs of the projects.

(4) Location and Hydraulic Design of Encroachments on Flood Plains, refer to 23 CFR part 650, subpart A.

(5) Procedures for Abatement of Highway Traffic Noise and Construction Noise, refer to 23 CFR part 772.

(6) Accommodation of Utilities, refer to 23 CFR part 645, subpart B.

(7) Pavement Design, refer to 23 CFR part 626.

(b) *Bridges and structures.* (1) For existing bridges originally designed to any edition of the AASHTO Standard Specifications for Highway Bridges, modifications may be designed to the Standard Specifications for Highway Bridges, 17th Edition, AASHTO, 2002 (incorporated by reference; see § 625.4(d)), or to the standards and specifications that are listed in § 625.4(b).

(2) AASHTO LRFD Bridge Construction Specifications, 3rd Edition, AASHTO, 2010, with 2010, 2011, 2012, and 2014 Interim Revisions (incorporated by reference; see § 625.4(d)).

(3) AASHTO LRFD Bridge Design Specifications, 7th Edition, AASHTO, 2014, with 2015 Interim Revisions (incorporated by reference; see § 625.4(d)).

(4) AASHTO LRFD Movable Highway Bridge Design Specifications, 2nd Edition, AASHTO, 2007, including

2008, 2010, 2011, 2012, 2014, and 2015 Interim Revisions (incorporated by reference; see § 625.4(d)).

(5) AASHTO/AWS D1.5M/D1.5: 2010 Bridge Welding Code, 6th Edition, AASHTO, 2011, with 2011 and 2012 Interim Revisions (incorporated by reference; see § 625.4(d)).

(6) D1.4/D1.4M: 2011 Structural Welding Code-Reinforcing Steel, American Welding Society, 2011 (incorporated by reference; see § 625.4(d)).

(7) Standard Specifications for Structural Supports for Highway Signs, Luminaires and Traffic Signals, 6th Edition, AASHTO, 2013 (incorporated by reference; see § 625.4(d)).

(8) Navigational Clearances for Bridges, refer to 23 CFR part 650, subpart H.

* * * * *

(d) *Documents incorporated by reference.* The Director of the Federal Register approves the incorporation by reference of the documents listed in this section in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The documents listed in this paragraph are incorporated by reference and available for inspection at the U.S. Department of Transportation's National Transportation Library at 1200 New Jersey Avenue SE., Washington, DC 20590; (800) 853-1351. The documents also are available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal-register/code_of_federal_regulations/ibr_locations.html. Copies of these documents may be obtained from the following organizations:

(1) American Association of State Highway and Transportation Officials (AASHTO), Suite 249, 444 North Capitol Street NW., Washington, DC 20001; www.transportation.org; or (202) 624-5800.

(i) A Policy on Geometric Design of Highways and Streets, 6th Edition, 2011.

(ii) A Policy on Design Standards Interstate System, January 2005.

(iii) Standard Specifications for Highway Bridges, 17th Edition, 2002

(iv) AASHTO LRFD Bridge Construction Specifications, 3rd Edition, 2010; with:

(A) Interim Revisions, 2010,

(B) Interim Revisions, 2011,

(C) Interim Revisions, 2012, and

(D) Interim Revisions, 2014.

(v) AASHTO LRFD Bridge Design Specifications, 7th Edition, 2014, with: (A) 2015 Interim Revisions.

(B) [Reserved].
(vi) AASHTO LRFD Movable Highway Bridge Design Specifications, 2nd Edition, 2007, with:
(A) Interim Revisions, 2008,
(B) Interim Revisions, 2010,
(C) Interim Revisions, 2011,
(D) Interim Revisions, 2012,
(E) Interim Revisions, 2014, and
(F) Interim Revisions, 2015
(vii) AASHTO/AWS D1.5M/D1.5: 2010 Bridge Welding Code, 6th Edition, 2010, with:

(A) Interim Revisions, 2011, and
(B) Interim Revisions, 2012
(viii) Standard Specifications for Structural Supports for Highway Signs, Luminaires and Traffic Signals, 6th Edition, AASHTO 2013.

(2) American Welding Society (AWS), 8869 NW 36 Street, #130 Miami, FL 33166-6672; www.aws.org; or (800) 443-9353 or (305) 443-9353.

(i) D1.4/D1.4M: 2011 Structural Welding Code—Reinforcing Steel, 2011.
(ii) [Reserved].

(e) The FHWA supports using, as design resources to achieve context sensitive designs, guides that national organizations develop from peer-reviewed research, or equivalent guides that are developed in cooperation with State or local officials, when such guides are not in conflict with Federal laws and regulations.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9719]

RIN 1545-BM62

Notional Principal Contracts; Swaps With Nonperiodic Payments

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations; correcting amendments.

SUMMARY: This document contains amendments to temporary regulations relating to guidance for the treatment of nonperiodic payments made or received pursuant to certain notional principal contracts. These amendments change the applicability date of the embedded loan rule for the treatment of nonperiodic payments from November 4, 2015, to the later of January 1, 2017, or six months after the date of publication of the Treasury decision adopting these rules as final regulations

in the **Federal Register**. The amendments to the temporary regulations provide guidance to taxpayers who are parties making and receiving nonperiodic payments under notional principal contracts.

DATES: *Effective Date:* These amendments are effective on October 13, 2015.

Applicability Date: For the date of applicability, see § 1.446-3T(j)(2), as corrected.

FOR FURTHER INFORMATION CONTACT: Alexa Dubert at (202) 317-6945 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations that are the subject of these amendments are under section 446(b) of the Internal Revenue Code (Code). The temporary regulations (TD 9719) were published in the **Federal Register** on Friday, May 8, 2015 (80 FR 26437).

Need for Amendments

Section 1.446-3T(g)(4)(i) of the temporary regulations provides that, subject to certain exceptions set forth in § 1.446-3T(g)(4)(ii), a notional principal contract with one or more nonperiodic payments is treated as two separate transactions consisting of an on-market, level payment swap and one or more loans (the embedded loan rule). Section 1.446-3T(g)(4)(i) eliminated the exception to the embedded loan rule for non-significant, nonperiodic payments set forth in the final regulations (TD 8491) published in the **Federal Register** on October 14, 1993 (58 FR 53125) (the 1993 Regulations). See § 1.446-3. Section 1.446-3T(g)(4)(i) applies to notional principal contracts entered into on or after November 4, 2015. After publication of the temporary regulations, the Treasury Department and the IRS received comments requesting the delay of the applicability date of the embedded loan rule set forth in the temporary regulations. In response to those comments, this document amends the applicability date to make § 1.446-3T(g)(4)(i) and § 1.446-3T(g)(6) *Example 2* apply to notional principal contracts entered into on or after the later of January 1, 2017, or 180 days after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. Prior to the date of applicability of § 1.446-3T(g)(4)(i), as corrected, taxpayers may continue to apply the 1993 Regulations that (except for purposes of section 956) limit the application of the embedded loan rule

to nonperiodic payments that are significant.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.446-3T is amended by revising paragraph (j)(2) to read as follows:

§ 1.446-3T Notional principal contracts (temporary).

* * * * *

(j) * * *

(2) *Application of § 1.446-3T(g)(4).* Paragraph (g)(4)(i) of this section and paragraph (g)(6) *Example 2* of this section apply to notional principal contracts entered into on or after the later of January 1, 2017, or 180 days after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. Paragraph (g)(4)(ii) of this section applies to notional principal contracts entered into on or after May 8, 2015. However, before the later of January 1, 2017, or 180 days after the date of publication of the Treasury decision adopting paragraph (g)(4)(i) of this section as final regulations in the **Federal Register**, taxpayers may rely on the provision in § 1.446-3(g)(4), as contained in 26 CFR part 1, revised April 1, 2015, which (except for purposes of section 956) limits the application of the embedded loan rule to nonperiodic payments that are significant, even if the requirements for the exceptions in paragraph (g)(4)(ii) of this section are not met. Taxpayers may apply paragraph (g)(4)(i) of this section, paragraph (g)(4)(ii) of this section, or both to notional principal contracts entered into before the dates set forth in this paragraph (j)(2).

* * * * *

Martin Franks,

Branch Chief, Publications & Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure & Administration).

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