NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, 32, 34, 39, 40, 70 and 150

[NRC–2025–1205]

RIN 3150–AL49

Modernizing NRC Regulations for Byproduct Material Use

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for the licensing of byproduct material, some source material, and some special nuclear material. The NRC's goal in amending these regulations is to modernize the safe, effective, and efficient use of licensed material. This action would reduce the burden of the NRC's licensing process, eliminate the need for certain exemptions from existing regulations, and eliminate unnecessary requirements. The NRC is seeking public comment on this proposed rule and draft interim guidance.

DATES: Comments must be submitted electronically using *https://www.regulations.gov* by 11:59 p.m. eastern time on July 2, 2026.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2025–1205, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously.

Follow the search instructions on *https://www.regulations.gov* to view public comments.

You can read a plain language description of this proposed rule at *https://www.regulations.gov/docket/NRC-2025-1205.* For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Amy McKenna, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001, Office of Nuclear Material Safety and Safeguards email: *amy.mckenna@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

A. Need for Regulatory Action

On May 23, 2025, President Trump signed Executive Order (E.O.) 14300, ''Ordering the Reform of the Nuclear Regulatory Commission.'' E.O. 14300 requires the NRC to undertake a review and wholesale revision of its regulations and guidance documents, after which it must issue notices of proposed rulemaking by February 23, 2026. Final rules and guidance to conclude the revision process must be issued no later than November 23, 2026. In accordance with E.O. 14300 the NRC identified changes across title 10 of the *Code of Federal Regulations* (10 CFR) parts 30, 31, 32, 34, 39, 40, 70, and 150. These changes would yield significant efficiencies and reduce regulatory burden for licensees, NRC, and Agreement States while upholding our shared commitment to public safety.

B. Major Provisions

Major provisions of this proposed rule include the following changes:

- Revised the table of radionuclide activity values used for determining decommissioning financial assurance (DFA) for sealed and unsealed radioactive materials.
- Established a new class of general licenses (GLs), called standard general licenses (SGLs), to address anti-competitive barriers.
- Streamlined requirements for the distribution of exempt byproduct material and source material.
- Established distribution pathways for microsources.
- Revised the definition of consortium to address anti-competitive barriers.
- Revised administrative requirements for industrial Radiography to reduce anti-competitive barriers and modernized the radiography regulations.
- Modernized well logging regulations.
- Streamlined requirements for Agreement State Licensees in 10 CFR part 150.

C. Costs and Benefits

The NRC prepared a draft regulatory analysis to determine the expected quantitative costs and benefits of this proposed rule, as well as qualitative factors to be considered in the NRC's rulemaking decision. The conclusion of the analysis is that this proposed rule and associated guidance would result in net savings to Industry, Agreement States, and the NRC of $2,987,000 using a 7-percent discount rate.

The draft regulatory analysis also considers, in a qualitative fashion, regulatory efficiency, and public confidence. This rulemaking will reduce the effort that applicants and licensees would need to expend to generate exemption requests and consider alternative means to accomplish the goals of current regulation. This rulemaking demonstrates the NRC's ability to effectively regulate applicants and licensees, including appropriate responses to statutory requirements.

The regulatory analysis is available as indicated in Section XVII, ''Availability of Documents,'' of this document.

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2025–1205 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2025–1205.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Search.'' For problems

with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.

- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.
- *Public Meeting:* The NRC may conduct a public meeting to describe the proposed amendments and answer questions from the public on the proposed rule. If the NRC determines it will hold a public meeting, NRC will publish a notice of the location, time, and agenda of the meeting on the NRC's public meeting website within 10 calendar days of the meeting. Stakeholders should monitor the NRC's public meeting website for information about the public meeting at: *https://www.nrc.gov/public-involve/public-meetings/index.cfm.*

B. Submitting Comments

Comments must be submitted electronically using *https://www.regulations.gov* no later than 11:59 p.m. eastern time on July 2, 2026. Please include Docket ID NRC–2025–1205 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Executive Order 14300: Ordering the Reform of the Nuclear Regulatory Commission

On May 23, 2025, President Donald J. Trump signed E.O. 14300, ''Ordering the Reform of the Nuclear Regulatory Commission.'' Section 5, ''Reforming and Modernizing the NRC's Regulations,'' requires the NRC to undertake a review and wholesale revision of its regulations and guidance documents as guided by the policies set forth in section 2 of the E.O. This rulemaking addresses section 5, which requires the NRC to ''undertake a review and wholesale revision of its regulations and guidance documents.''

III. Background

Within the National Materials Program, the NRC regulates the use of byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass for a variety of uses as authorized by Sections 53, 63, and 81 of the Atomic Energy Act of 1954, as amended (AEA) and pursuant to 10 CFR parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70 and 150. For the purposes of this document, ''byproduct material,'' ''source material,'' and ''special nuclear material'' describe three broad categories of radioactive material regulated under the AEA: (1) radioactive material created, made radioactive, or generated as waste from nuclear processes (byproduct material); (2) naturally occurring uranium and thorium (source material); and (3) processed or enriched nuclear materials used for reactor fuel or other applications (special nuclear material). These categories are defined in NRC regulations, §§§ 30.4, 40.4, 70.4. These materials have many different uses, including use in industrial radiography, moisture-density gauges, medical applications, and well logging. Currently, the NRC has approximately 2,700 active specific licenses for the use and possession of byproduct, source, and certain quantities of special nuclear material. The applicable NRC regulations and specific license conditions establish the requirements for the safe handling, use, and storage of these materials. The NRC inspects facilities to ensure compliance with regulations and takes action when violations occur. The public also uses exempt quantities of byproduct material and source material in consumer products such as smoke detectors, static eliminators and self-luminous products.

Under Section 274b of the AEA, States can enter into Agreements with the NRC that allow States to assume, and the NRC to discontinue, regulatory authority over byproduct, source, and small quantities of special nuclear material. Known as Agreement States, these States can then regulate byproduct, source, and certain quantities of special nuclear materials that are covered in the Agreement, using their own legislation, regulations, or other legally binding provisions. The NRC enters into an Agreement if the Commission finds the State program adequate to protect public health and safety and compatible with the NRC's regulatory program. The NRC ensures that an Agreement State program remains adequate and compatible through periodic review and assessment under the Integrated Materials Performance Evaluation Program (IMPEP). There are currently 40 Agreement States, which regulate approximately 20,000 materials licensees.

In response to several recent E.O.s, including E.O. 14300, the NRC identified requirements within 10 CFR parts 30, 31, 32, 34, 39, 40, and 150 that could be revised, deleted, or modified in order to meet the E.O. objectives. The following sections provide background information on the affected parts. Section IV of this document provides discussion on the specific proposed changes for each of the affected parts.

A. Part 30 Reducing Anti-Competitive Barriers in Consortium Definition

The NRC is proposing to revise its definition of consortium to remove the anti-competitive barrier limitation that a positron emission tomography (PET) radionuclide production facility must be in the same geographical area as the medical use licensee to be considered a consortium. The limitation that the PET production facility had to be located in the same geographical area as the medical use licensee severely limited licensees from locating their PET radionuclide production facility in the most cost-effective location and was based primarily on the short half-life of PET radionuclides, making distant transport impracticable.

B. Part 30 Modernizing Appendix B and Part 70 Quantities of Licensed Material Used To Assess Financial Assurance for Decommissioning

The NRC is proposing to revise the table of radionuclide activity values used for determining decommissioning financial assurance (DFA) for sealed and unsealed radioactive materials. The proposed rule would revise the current table in appendix B, ''Quantities of Licensed Material Requiring Labeling,'' to 10 CFR part 30, ''Rules of General

Applicability to Domestic Licensing of Byproduct Material,'' by replacing its applicable values from the table in appendix C, ''Quantities of Licensed Material Requiring Labeling,'' to 10 CFR part 20, ''Standards for Protection against Radiation.'' This would add radionuclides not currently listed in appendix B to 10 CFR part 30, including radionuclides associated with industrial technologies and current and emerging medical uses. These changes would generally reduce DFA requirements for most licensees and eliminate the need for certain exemptions. In addition, the NRC would remove all radionuclides with a half-life of 120 days or less from the appendix, since these radionuclides are not considered when developing DFA, and amend the title of the table to ''Quantities of Licensed Material Used to Assess Financial Assurance for Decommissioning,'' to more accurately reflect its current use for DFA. The default values would remain at their current values. The NRC is proposing to revise § 70.25 to match the proposed changes to appendix B to part 30.

C. Part 31 Creating New Classes of General Licenses and Modernization of Current Classes of General Licenses

The NRC is proposing to establish a new class of general licenses (GLs), called standard general licenses (SGLs), to address anti-competitive barriers. The proposed framework would permit GLs for portable gauges, additional fixed gauges, a subset of diagnostic medical uses, additional analytical instruments, and additional in vitro testing. The SGLs would be granted by regulation, and requires submission of a registration, fee, and certification of understanding. Proposed rule language, found in §§ 31.13 through 31.18, is based on standard license conditions and essential standard commitments related to programs necessary for radiological safety and security. Conforming changes are proposed in other parts of 10 CFR parts 30 and 32 to ensure radioactive materials can be distributed to and from the standard general licensees. The SGL pathway would create a second option for licensing such that entities could select between a SGL or a specific license for certain activities. The specific license pathway for entities wishing to conduct activities in a non-standard manner or outside of the normal conditions would be preserved so as to not limit flexibility. However, licensees could select the lower regulatory burden standard general licensing pathway if they are able to conduct activities within the framework of the SGL for their specified activity.

Additionally, the NRC is proposing to amend requirements in 10 CFR part 31, ''General Domestic Licenses For Byproduct Material,'' to permit electronic transmission of registrations for § 31.5 registerable devices, harmonize holding periods with decommissioning timelines in § 30.36, align physical inventory frequencies with equivalent physical inventory limits for specific licenses, and harmonize in vitro test vial limits with labeling limits in 10 CFR part 20.

D. Parts 32 and 40 Reducing Reporting Requirements for Consumer Products Containing Small Quantities of Radioactive Material

The NRC is proposing to amend several regulations governing the distribution of exempt byproduct material and source material. This proposed rule would eliminate the requirements under 10 CFR part 32, ''Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material,'' and 10 CFR part 40, ''Domestic Licensing of Source Material,'' that require licensees to submit an annual report of transfers to the NRC. The elimination of these requirements would reduce the licensee's burden of preparing and providing records and would reduce the burden of the NRC to collect, manage, and store the reports while still remaining protective of public health and safety given that the NRC will still maintain access to the information.

E. Part 32 Expanding Distribution Pathways for Microsources

The NRC is proposing to amend requirements in § 32.72 to include microsources, such as radioactive microspheres, within its scope, which would allow commercial radiopharmacies to prepare and distribute these materials. The proposed rule would expand eligibility to any applicant legally authorized under applicable Federal or State law to manufacture, compound, prepare, or distribute radioactive drugs or medical devices, providing flexibility for future distribution pathways authorized by the U.S. Food and Drug Administration (FDA) or State regulatory bodies. In addition, the NRC is proposing to revise § 32.74 to clarify that it may also be used to distribute microsources and authorize distribution to any licensee authorized to use the source or device under 10 CFR part 35, ''Medical Use of Byproduct Material,'' without limitation to specific subparts. These changes would allow for smooth distribution of microsources to medical use licensees.

F. Part 34 Reducing Anti-Competitive Barriers and Administrative Requirements for Industrial Radiography

The NRC is proposing to amend the requirements associated with industrial radiography operations in 10 CFR part 34, ''Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations.'' These revisions to the proposed rule would address anti-competitive barriers due to overly prescriptive performance requirements for industrial radiography equipment, provide clarity regarding ambiguous language in the two-person rule, and reduce or remove administrative and obsolete requirements. These proposed changes would reduce the regulatory burden on licensees and applicants by reducing or eliminating administrative requirements for recordkeeping and notifications. Additionally, revisions to the performance requirements for industrial radiography equipment would remove the need to meet the requirements in American National Standards Institute (ANSI) N432–1980, ''Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography'' and replace them with requirements to register the device in accordance with § 32.320 of this section. These changes will ensure that radiation safety is maintained while reducing anti-competitive regulatory barriers and allowing for innovation in the design of radiography equipment.

G. Part 39 Modernizing Well Logging Regulations

The NRC is proposing to amend the rules associated with well logging in 10 CFR part 39, ''Licenses and Radiation Safety Requirements for Well Logging.'' These revisions to the proposed rule would remove or modify redundant and unnecessary regulations regarding the use of nuclear material in well logging operations that support the oil and gas exploration industry. The proposed rule would revise leak testing requirements to allow for the sealed source leak testing frequency in accordance with the Sealed Source and Device Registration (SSDR), extend the survey meter calibration frequency in § 39.33 from 6 months to 12 months, and eliminate unnecessary notifications. These changes would reduce the regulatory burden on licensees by reducing or eliminating administrative requirements and notifications while maintaining safety.

H. Part 150 Modernizing Requirements for Agreement State Licensees in Part 150

The NRC is proposing to amend the rules in 10 CFR part 150, ''Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274,'' to remove the requirement for Agreement State licensees using special nuclear material of low strategic significance to meet the physical protection requirements in 10 CFR part 73, ''Physical Protection of Plants and Materials.'' Forty years of operational experience has demonstrated that this material is adequately secured under the Agreement State oversight. Additionally, the NRC is proposing to amend the requirements in § 150.20 to reduce the amount of time an Agreement State licensee has to file for reciprocity before initiation of work activities in an NRC jurisdiction, eliminate the need to notify the NRC of location changes for work in offshore waters, and allow SGLs to be recognized by the NRC for the purposes of reciprocity. This action would reduce administrative burden on the applicant and the NRC while maintaining safety.

IV. Discussion

The NRC, as directed in E.O. 14300, Section 5, undertook a review of its regulations of the use of byproduct, source, and special nuclear material. The NRC's goal in its review was to identify in its regulations areas that could be modernized while ensuring the continued safe, effective, and efficient use of byproduct material. The NRC has identified changes which would yield significant efficiencies and reduce regulatory burden for licensees, NRC, and Agreement States while upholding our shared commitment to public safety. These actions would reduce the burden of the NRC's licensing process, eliminate the need for certain exemptions from existing regulations, and eliminate unnecessary requirements

Each section presents information on a different part impacted by the proposed rule, detailing what action the NRC is proposing and whom the action affects and how.

The NRC prepared an unofficial redline strikeout version of the proposed changes to regulatory text that is intended to help the reader identify the proposed changes. The unofficial redline strikeout version of the proposed rule is publicly available and is listed in the ''Availability of Documents'' section.

Part 30 Reducing Anti-Competitive Barriers in Consortium Definition

On October 1, 2007, the NRC published a final rule (72 FR 55864) to amend 10 CFR part 30 to implement provisions of the Energy Policy Act of 2005 (EPAct). The amendments included a revision to § 30.4 to add a definition for the term ''consortium.'' Under the definition in 10 CFR 30.4, a consortium was an association of medical use licensees and a PET radionuclide production facility located at an educational institution, Federal facility, or noncommercial medical facility ''in the same geographical area'' that jointly own or share the operation and maintenance costs of the facility. The rule provided regulatory relief to consortia engaged in the noncommercial production and distribution of PET radionuclides for medical use, including authorization for noncommercial transfers under § 30.32(j) without requiring a separate distribution license under § 32.72. The geographical limitation was included due to the short half-lives of PET radionuclides, such as fluorine-18 (1.8 hours) and carbon-11 (20 minutes), which require rapid production and delivery to ensure timely medical use. However, there was no safety reason provided for the limitation and it was based on the supply chain difficulties associated with short-lived radionuclides. While some changes in the medical use of byproduct material have introduced longer lived PET radionuclides into use, such as copper-64 (12.7 hours), the NRC has determined that licensees and regulators have found the phrase ''geographical area'' lacks clarity as to when consortium relief applies. In addition, requiring the PET production facility to be located in the same geographic area, when safe transfer of PET radionuclides can occur following all other applicable requirements, unnecessarily inhibits licensees' ability to establish or participate in cost-effective, collaborative PET radionuclide production arrangements.

The NRC proposes a revision to § 30.4 to change the definition for the term ''consortium.'' The definition would support the regulation of accelerator-produced radioactive materials, including PET radionuclides used in medical imaging. Under the proposed definition, a consortium would be an association of medical use licensees and a PET radionuclide production facility that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in radioactive drugs within the consortium for noncommercial distribution among its associated members for medical use. The proposed rule would remove the requirement to be in the same geographical area and would provide regulatory relief to consortia engaged in the noncommercial production and distribution of PET radionuclides for medical use, including authorization for noncommercial transfers under § 30.32(j) without requiring a separate distribution license under § 32.72.

Part 30 Modernizing Appendix B and Part 70 Quantities of Licensed Material Used To Assess Financial Assurance for Decommissioning

Decommissioning financial assurance is a guarantee or other financial agreement provided by a licensee to ensure that sufficient funds are available to complete decommissioning activities in a safe and timely manner. The NRC's regulations in §§ 30.35 and 70.25, ''Financial assurance and recordkeeping for decommissioning,'' provide tables of required funds that need to be saved by each licensee. These regulations rely on the values provided in appendix B to 10 CFR part 30 when determining the amount of DFA required for unsealed and sealed byproduct material and unsealed special nuclear material. As noted in §§ 30.35(a)(1) and 70.25(a)(2), a decommissioning funding plan (DFP) must be submitted when unsealed radionuclide activities exceed 1×10^5 times the applicable quantities listed in appendix B to 10 CFR part 30 and fixed amounts of DFA are required when unsealed radionuclide activities exceed 1×10^3 times the applicable quantities listed in that appendix B to part 30. Individuals with licenses authorizing the possession and use of sealed sources or plated foils at quantities 1×10^{12} times the values in appendix B to 10 CFR part 30 must also submit DFPs and fixed amounts of DFA are required when radionuclide activities in sealed sources or plated foils exceed 1×10^{10} times the applicable quantities listed in appendix B to part 30. The potentially affected licensees are those authorized to possess licensed materials above these limits.

Appendix B to 10 CFR part 30 includes default possession values for radionuclides not specifically listed. The default possession values are equal to the lowest values listed in appendix B to 10 CFR part 30 for specific alpha, beta, and gamma-emitting radionuclides. Use of the default values may result in licensees needing more DFA than is warranted based on the risk to public health and safety. For example, a licensee possessing more

than 0.1 millicurie (mCi) but less than 1 mCi of an unsealed non-alpha-emitting isotope, would be required under § 30.35(d) to provide $225,000 in DFA. To possess more than 1 mCi of the non-alpha-emitting isotope, a licensee would be required to provide $1,125,000 in DFA, and a DFP would be required to possess more than 10 mCi. However, if the NRC revised appendix B to 10 CFR part 30 to adopt the values in appendix C to 10 CFR part 20, the minimum possession threshold for DFA or a DFP would increase 100-fold for accelerator-produced radioactive material (NARM) isotopes germanium (Ge)-68, gold-195, and sodium-22. Therefore, the application of the current generic default possession values creates a regulatory burden by requiring licensees to provide decommissioning funding that is not commensurate with the risk of isotope-specific possession values.

In a petition for rulemaking (PRM) docketed as PRM–30–66, the Organization of Agreement States (OAS) requested that the NRC provide specific possession values for naturally occurring and NARM radionuclides that are not currently listed in appendix B to 10 CFR part 30 so that licensees using these isotopes, especially medical licensees, would not have to apply the appendix's default values to calculate decommissioning funding requirements. The OAS stated that patient health and safety are being compromised due to delays in licensing important diagnostic and therapeutic products that use radionuclides not listed in appendix B to 10 CFR part 30, and that these licensing obstacles could discourage the development of new medical and industrial applications. The OAS also suggested that, rather than issuing exemptions on a case-by-case basis, the more appropriate way to address the inconsistency in appendix B to 10 CFR part 30 is to amend the regulation to add appropriate radionuclides and their corresponding activities.

The NRC is proposing to update appendix B to 10 CFR part 30, ''Quantities of Licensed Material Requiring Labeling,'' with radionuclides and values from appendix C to 10 CFR part 20, ''Quantities of Licensed Material Requiring Labeling'' for values that are equal to or higher than the current default value in appendix B to 10 CFR part 30. This would add radionuclides not currently listed in appendix B to 10 CFR part 30, including radionuclides associated with industrial technologies and current and emerging medical uses.

The proposed revisions to the list of radionuclides in appendix B to 10 CFR part 30 would align with the NRC's regulatory authority under the EPAct. The EPAct amended the definition of byproduct material to include NARM radionuclides and provided the NRC authority over this new category of byproduct material. Germanium (Ge)-68 and gallium (Ga)-68, radionuclide generators are of particular concern to those in the medical field since Ge-68 is not listed in appendix B to 10 CFR part 30 and the default values resulted in overly conservative decommissioning financial assurance requirements. In the report, ''Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) Final Report,'' dated August 12, 2015, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) concluded that the restrictive aspects of a DFP for Ge-68/Ga-68 generators that arise from the current 10 CFR part 30 regulations were preventing or deterring the use of promising Ga-68 diagnostic imaging agents for patients and recommended that the NRC address the DFP concerns relative to Ge-68/Ga-68 generators through rulemaking. The NRC has granted a limited number of exemptions for licensees that use Ge-68/Ga-68 generators under certain conditions. These exemptions were approved in advance of this rulemaking. By providing a regulatory solution through rulemaking, the NRC would create a more stable regulatory framework for applicants, licensees, and regulators. In cases where the values in appendix C to 10 CFR part 20 are lower than the values currently listed in appendix B to 10 CFR part 30, the NRC proposes maintaining the current values in appendix B to 10 CFR part 30. This means the values listed in appendix B to part 30 would align with the majority of values listed in appendix C to part 20 except for americium-241, cadmium-109, plutonium-239, uranium-233, uranium-234, uranium-235, zirconium-93, the default value for any alpha-emitting radionuclide not listed or mixtures of alpha emitters of unknown composition, and the default value for any radionuclide other than alpha emitting radionuclides not listed or mixtures of beta emitters of unknown composition which would remain at their current values.

Each of the values that would remain at their current values are a factor of 10 higher than what is listed in appendix C to 10 CFR part 20. If the values for these radionuclides were adopted from appendix C to 10 CFR part 20, then the values would decrease, and several licensees would become subject to DFA requirements. This would result in an undue burden to this population of licensees in obtaining DFA or requesting an exemption from the requirements. Since implementing DFA requirements in 1988, the NRC has not identified any instance where a licensee with these radionuclides has had insufficient DFA or any negative safety consequences because of insufficient DFA.

Because there is no safety related reason to decrease any values listed in appendix B to 10 CFR part 30, the NRC proposes maintaining status quo for the values for americium-241, cadmium-109, plutonium-239, uranium-233, uranium-234, uranium-235, zirconium-93, the default value for any alpha-emitting radionuclide not listed or mixtures of alpha emitters of unknown composition, and the default value for any radionuclide other than alpha emitting radionuclides not listed or mixtures of beta emitters of unknown composition in appendix B to 10 CFR part 30. The default values in appendix B to 10 CFR part 30 remain at their current values. These changes will either reduce or not affect the amount of DFA required for licensees, depending on the mixture of radionuclides the licensee possesses.

Finally, the NRC would remove all radionuclides with a half-life of 120 days or less from the updated appendix B to 10 CFR part 30 because these radionuclides are not considered when developing DFA. Additionally, the NRC is also proposing a revision to § 70.25(a)(2) and (b) to specify unsealed special nuclear material ''of half-life greater than 120 days.'' NRC experience shows that short-lived radionuclides do not require major decommissioning efforts, as radionuclides with half-lives of 120 days or less naturally decay to negligible levels within a few years.

This rulemaking also includes changing the title to appendix B to 10 CFR part 30 to clarify the intent and purpose of the appendix. Appendix B to 10 CFR part 30 is used solely for the purpose of calculating the required amounts of DFA. Therefore, this proposed rule would change the title of appendix B to 10 CFR part 30 from ''Quantities of Licensed Material Requiring Labeling'' to ''Quantities of Licensed Material Used to Assess Financial Assurance for Decommissioning.''

These proposed revisions address the changes requested in PRM–30–66 from the OAS requesting that the NRC conduct rulemaking to provide an expeditious solution to the DFA concerns of applicants and licensees who currently use, or plan to use, the unlisted NARM radionuclides, especially in the diagnosis and treatment of diseases.

Under current requirements, licensees may choose to submit either a DFP under § 30.35(e) or a certification that financial assurance for decommissioning has been provided in the amount prescribed by § 30.35(d). Although medical licensees generally possess smaller quantities of radioactive material than major nuclear facilities and typically use certifications under § 30.35(d), they may possess unsealed radionuclides with half-lives greater than 120 days and thus could develop facility-specific decommissioning cost estimates in accordance with § 30.35(e). While the review and approval of DFPs under § 30.35(e) could be resource intensive for both the applicant or licensee and the regulatory agency, some licensees might find the submission of a DFP more cost effective than the certification of financial assurance for decommissioning using DFA values based on the default radionuclide threshold values in appendix B to 10 CFR part 30. The proposed changes to radionuclide values in appendix B to 10 CFR part 30 would decrease, or maintain, the amount required for decommissioning financial assurance for an individual NRC 10 CFR part 30 licensee. After evaluating the impact of the proposed provisions on their decommissioning financial assurance mechanism, a licensee may be required to make revisions that lead to additional costs. However, the NRC expects that most 10 CFR part 30 licensees would benefit from these changes. This was demonstrated both by the petition that initiated the rulemaking and by the public responses to the draft regulatory basis supporting a rulemaking on decommissioning financial assurance for sealed and unsealed radioactive materials (87 FR 25157).

NRC licensees under subpart H of 10 CFR part 70, as required by § 70.25(b) must submit DFPs. The changes to appendix B to 10 CFR part 30 would not impact 10 CFR part 70 licensees, as their possession quantities exceed the threshold identified in § 70.25(d).

Under the proposed rule all affected licensees would be required to review the updated appendix B to 10 CFR part 30 to determine whether changes are needed. Licensees that no longer require DFA or a DFP or could decrease their DFA, could do so voluntarily at their discretion after the effective date of the rule. Licensees would need to request NRC approval when making any changes to their DFAs or DFPs. For licensees where no change is required, the NRC would verify compliance during triannual reviews and as part of routine inspection activities.

Part 31 Creating New Classes of General Licenses and Modernization of Current Classes of General Licenses

A. Standard General Licenses (SGL)

Consistent with its authority under the AEA, the NRC may issue general or specific licenses for the use of byproduct, source, and certain quantities of special nuclear material. A specific license is issued to a named entity after the filing of an application with the Commission. Additionally, amendments to specific licenses are required when a variety of changes occur. In the case of applications and amendments, the NRC and licensee engage in back and forth communication until a licensing basis is solidified and documented in a licensing document. Specific licenses cover a wide range of activities of byproduct material and have a variety of associated risk profiles. Some activities are conducted in a standard method across the industry, while others are conducted in a non-uniform manner. The specific licenses for standard operations use consistent license authorizations and conditions, such that, these specific licenses appear almost identical across the industry with the exception of individuals named on the license and the locations authorized by the license. For example, the majority of specifically licensed portable gauge licensees operate under the same license conditions and have the same license commitments. The burden associated with applying for a specific license and maintaining a specific license is unnecessarily high for low risk, standard operations when the specific license follows the standard format.

A GL is issued by regulation and grants authority to entities conducting the activities specified in the regulation issuing the GL. Requirements for general licensees appear in the regulations and are designed to be commensurate with the specific activities covered by the GL. A GL is effective without the need for a user to file an application with the Commission or the issuance of a licensing document to a particular person. However, certain GLs may require registration with the Commission. Under 10 CFR part 31, the Commission grants GLs for certain uses of byproduct material and provides the requirements associated with these GLs. This regulatory framework has proven to be effective and a low burden for many low risk, standard activities.

The NRC is proposing to create a new class of GLs within subpart C of 10 CFR part 31 for a subset of low-risk activities that are currently specifically licensed, including fixed gauging, portable gauging, certain medical uses, certain analytical equipment uses, and certain in vitro testing uses. The impacted groups would be permitted to choose between two licensing pathways. An SGL would require submission of a registration, fee, and certification of understanding for five types of technology. The NRC is proposing that each type of technology has requirements codified in a separate regulation. For example, the NRC is proposing requirements for a Standard General License for Certain Fixed Gauging in § 31.14, a Standard General License for Portable Gauging in § 31.15, a Standard General License for Certain Medical Uses in § 31.16, a Standard General License for Certain Analytical Equipment Including Electron Capture Detectors, X-Ray Fluorescence Devices, and Ion Generators in § 31.17, and a Standard General License for Certain In Vitro Testing in § 31.18. The NRC is proposing administrative requirements, such as notifications and decommissioning, applicable to each of the SGLs in § 31.13.

The proposed rule language is based on standard license conditions and essential standard commitments related to programs necessary for radiological safety and security. The standard license conditions and essential standard commitments were derived from risk significant elements of NUREG–1556, ''Consolidated Guidance About Materials Licenses''. Elements taken from program specific NUREG–1556 Volumes and codified in the rule come from the ''Response from Applicants'' sections of NUREG–1556 and revolve around establishing programs, processes, and procedures to safely conduct licensed activities. These sections are tied to regulatory requirements in 10 CFR that are general in nature so NUREG–1556 provides methodologies to meet the general requirements for the safe conduct of licensed activities.

The proposed rule language requires, by reference, compliance with applicable regulations found in other applicable parts of 10 CFR to ensure the new general licensees comply with all applicable provisions that they are currently subject to by their specific licenses. In addition, the NRC is proposing inventory limitations in § 31.13(c) that would prohibit a single general licensee from aggregation of materials requiring implementation of requirements contained in 10 CFR part 37, materials requiring a decommissioning plan or financial assurance, and materials requiring an emergency plan. The GLs would not be

subject to any requirements beyond what is currently required to obtain a specific license. Under this proposed rule, entities would still have the flexibility to choose to obtain a specific license.

The NRC is proposing conforming changes in other parts of 10 CFR to ensure radioactive materials can be distributed to and from the new GLs. Conforming changes include: the definition of principal activities in § 30.4, addition of SGLs to § 30.6, addition of SGLs in § 30.34(h)(1), addition of SGLs to § 30.35(g), addition of SGLs to § 30.41(d)(1), addition of Standard General License for Certain Medical Uses to § 32.72(a), addition of Standard General License for Certain Medical Uses to § 32.74(a), and addition of SGLs in § 150.20.

Overall, the SGL pathway would reduce the burden on the licensee as well as the NRC while maintaining adequate safety, security, and oversight of these licensed activities. The current licensing pathway would exist as it does today, so no impact may be observed to licensees who chose to remain specifically licensed. However, licensees could select the SGL pathway if they are able to conduct activities within the framework of the SGL for their specified activity. The SGL option would have a lower application fee, lower annual fee, and would eliminate the need to submit licensing correspondence such as amendment requests. Instead of amendments, a notification process would be used for specified program changes. The SGLs would be subject to an inspection program that is equivalent to the inspection for the same specifically licensed activities. As part of the NRC's response to the ADVANCE Act of 2024, the NRC is reviewing current inspection programs including the frequency of inspection conducted under Inspection Manual Chapter 2800, ''Materials Inspection Program''.

B. Current Classes of General Licenses—10 CFR 31.5 Licensees

General licenses in § 31.5 currently authorize use of certain devices. The NRC is proposing changes to these requirements to reduce burden while maintaining protection of public health and safety.

Currently, registrations for generally licensed devices as required by § 31.5(c)(14) must be submitted to the Commission by mail. However, most entities subject to this requirement use electronic communications as their primary communication method. The NRC is proposing to amend § 31.5(c)(14) to add electronic communication methods, such as email, as permitted communication methods. Additionally, the NRC is proposing to add a mailing address that is compatible for signature required correspondence should an entity wish to send their registration as signature required.

Currently, § 31.5(c)(15) permits general licensees to hold devices for a period of no longer than 2 years. The term hold is used to describe a licensee's action of keeping a device in its possession that is no longer in use and no longer planned to be used; this is typically the period where a device is out of service prior to disposal of the device. This has shown to be constraining to business operations since entities may need to hold devices for longer than 2 years. For example, an entity may take a device out of service with the intention of disposing of it. However, it may take longer than 2 years to solicit bids for disposal, obtain a contract, and complete the disposal. The NRC is proposing to amend § 31.5(c)(15) to revise the holding period for GLs from 2 years to 36 months. Additionally, holding periods for generally licensed devices are based on decommissioning time periods for many types of specific licensees. Currently, the time period in § 30.36(d) and § 31.5(c)(15) is 2 years. However, as part of its response to E.O. 14300, the NRC is considering increasing this time period to 3 years.

Currently, § 31.5(c)(15) requires general licensees to perform quarterly physical inventory on devices that are placed on standby. The term standby is used to describe a licensee's action of keeping a device in their possession that they plan to return to service and use in the future. However, the regulatory framework for sealed sources that have fewer inherent safety features require physical inventories every 6 months. For example, sealed sources possessed by medical licensees are subject to § 35.67 which requires physical inventories of sealed sources at a semi-annual periodicity. Similarly, licensed materials in well-logging activities are subject to § 39.37 which requires physical inventories of licensed material at a semi-annual periodicity. Additionally, the majority of sealed sources possessed by specific licensees are subject to semi-annual physical inventories through license conditions based on the applicable volume of the NUREG–1556 series, ''Consolidated Guidance About Materials Licenses.'' A quarterly physical inventory is overly burdensome and restrictive in comparison to the Commission's holistic regulatory framework related to physical inventories. The NRC is proposing to amend § 31.5(c)(15) to change the physical inventory frequency from quarterly to semi-annually for devices on standby. By changing the periodicity to semi-annually, the NRC would ensure consistent requirements are imposed across various licensee populations in regard to physical inventory requirements. Specifically, the risk profile for generally licensed devices is lower than the risk profile for specifically licensed devices for which a semi-annual inventory is required for sealed sources. Since the inception of the generally licensed device program in the 1970s, the NRC has obtained sufficient operating experience to demonstrate that this population of licensees generally has adequate material control and accountability such that quarterly inventories are not necessary.

These changes would affect entities required to register devices under § 31.5. Affected entities currently include holders of certain generally licensed devices. The changes would provide flexibility to the communication methods permitted, which increase efficiency, and save entities the cost of mailing physical copies. Additionally, the changes to holding periods would provide flexibility to entities by allowing them to hold devices for a longer time period before disposal is required, should the time period for decommissioning increase. Finally, the change to physical inventories would reduce the number of times per year that an entity must conduct a physical inventory of their generally licensed devices. This would cut the time spent on physical inventories in half.

C. Current Classes of General Licenses—10 CFR 31.11 Licensees

Currently, § 31.11(a) limits the total activity per vial for in vitro clinical or laboratory testing for certain persons, including physicians. The limit for carbon-14 is 10 microcuries, the limit for hydrogen-3 is 50 microcuries, the limit for selenium-75 is 10 microcuries, and the limit for cobalt-57 is 10 microcuries. Meanwhile, 10 CFR part 20 only requires labeling for quantities that are above these activities. Specifically, 10 CFR part 20 appendix C requires labeling for carbon-14 at 100 microcuries, hydrogen-3 at 1,000 microcuries, selenium-75 at 100 microcuries, and cobalt-57 at 100 microcuries. Additionally, § 30.71 Schedule B provides exempt quantity thresholds that are higher than the GL limits. Specifically, § 30.71 Schedule B states the exempt quantity limit for carbon-14 is 100 microcuries, hydrogen-3 is 1,000 microcuries, selenium-75 is

10 microcuries, and cobalt-57 is 100 microcuries. The conflict between exempt quantities in § 30.71 Schedule B and the values in § 31.11(a) pose an unclear regulatory framework for entities working with quantities above the vial limit, but below the exempt quantity limit.

The NRC is proposing to amend § 31.11(a) to increase the prepackaged unit limit from 10 microcuries to 100 microcuries for carbon-14, from 50 microcuries to 1,000 microcuries for hydrogen-3, from 10 microcuries to 100 microcuries for selenium-75, and from 10 microcuries to 100 microcuries for cobalt-57.

The proposed change would affect entities that are currently required to obtain a specific license for in vitro testing to use prepackaged units above the current limits and instead would allow entities to handle prepackaged units with higher activity under a GL. Additionally, it would provide clarity to the licensee community since the current limits in § 31.11 for carbon-14, hydrogen-3, selenium-75, and cobalt-57 are below the exempt quantity limits in 10 CFR part 30 Schedule B or below the limits requiring labeling in 10 CFR part 20 appendix C.

Finally, physician is currently defined in §§ 30.4 and 35.2. With various rulemakings in progress to meet the requirements of E.O. 14300, divergent definitions across the byproduct material regulatory framework could emerge if the definition in 10 CFR part 35 is revised without also revising the definition in 10 CFR part 30 in parallel. The NRC is proposing conforming changes in § 30.4 to remove the definition of physician as it is already defined in 10 CFR part 35 and not used in 10 CFR part 30. This would increase regulatory clarity and ensure one single definition is present within the NRC's byproduct material regulatory framework.

Part 32 and 40 Reducing Reporting Requirements for Consumer Products Containing Small Quantities of Radioactive Material

In this rulemaking, the NRC is proposing to remove certain reporting requirements, while still requiring the information be maintained and available for review by the NRC, to ensure regulatory requirements are commensurate with risk and information needs. On March 24, 1983, the NRC published a final rule (48 FR 12331) to amend 10 CFR part 32. The amendments to 10 CFR part 32 included modifications to the reporting and recordkeeping requirements for licensees authorized to distribute consumer products containing small quantities of byproduct material (exempt items). Prior to this change, these regulations required licensees to submit an annual report to the NRC specifying the total quantity of byproduct material transferred to each type of consumer product and the total number of each product transferred during the reporting period. An annual report was required even if a licensee made no transfers during the reporting period. Under the rule, licensees were required to submit a report every five years, or at the time of application for renewal of the specific license, or at the time the licensee notifies the NRC that it is discontinuing distribution of these consumer products.

On October 16, 2007, the NRC published a final rule (72 FR 58473) to amend 10 CFR part 32, changing the reporting requirements back to an annual basis and to include details on what information should be included in the report. The rationale provided in the 2007 final rule was that changing back to annual reporting cycle, instead of a 5-year-cycle, would provide timely information for the NRC to fully determine the products and amount of byproduct material distributed annually which impacted the efforts of developing the NUREG–1717, ''Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials,'' and contributed to uncertainties in the results.

With respect to source material, on May 29, 2013, the NRC published a final rule (78 FR 32310) to amend 10 CFR part 40. The amendment required licensees to obtain a specific license rather than be permitted to operate under a GL. The amendment also included conditions for the initial distributor such as requirements for reporting and recordkeeping. The rule required that initial distributors of products used under an exemption in § 40.13(c) submit a report of transfer each year, following the same practice as consumer products distributed under 10 CFR part 32.

Since 2013, the NRC has not received complete or timely information regarding products and materials containing byproduct material and source material distributed for use under exemptions from licensing, despite the annual reporting frequency required under the 2007 and 2013 final rules. While the reevaluation of the reporting requirements suggested that annual reporting and additional information to be provided would improve inefficiencies in data collection, these issues have not been resolved. Licensees have not provided information clearly and consistently. There are also programmatic implementation issues in the collection, management, and storage of these reports. The intent of the information was to have readily available data to assess public exposure to radiation from these products and inform the Commission on the extent of distribution, if needed. However, this information, while useful, has been seldomly used. The NRC maintains the same access to the data by requesting information from the licensee when the need arises, instead of requesting a formal report to be submitted annually. Furthermore, the NRC has decades of data that can be used to support gaps in assessing public dose.

The NRC is proposing updating the regulations in §§ 32.12, 32.16, 32.20, 32.25(c), 32.29(c), and 32.32(c) to remove the annual reporting requirements. With this proposed change, licensees would be required to maintain the records of transfer per the record retention policy in § 30.51 and make the information available to the NRC upon request.

The elimination of the reporting requirements would reduce the licensee's burden of preparing and providing records and would reduce the burden of the NRC to collect, manage, and store the reports while still remaining protective of public health and safety given that the NRC will still maintain access to the information. This change would also be applicable to exempt products under 10 CFR part 40 and the required reporting under § 40.53(c). For exempt products under 10 CFR part 40, records would need to be maintained in accordance with § 40.61 and made available to the NRC upon request.

This proposed change would affect specific licensees who maintain a license under §§ 32.11, 32.14, 32.22, 32.26, 32.30, and 40.52 for distribution of consumer products under 10 CFR part 30 or 10 CFR part 40. Licensees would no longer have to submit an annual report to the NRC. Record retention policy would follow the regulations in §§ 30.51 and 40.61, for byproduct and source material respectively. This would allow the NRC to have access to information when needed, while at the same time reducing the burden on licenses in preparing and submitting the reports. Requesting the information when needed may introduce some burden due to unscheduled data collection, but it would be outweighed by the reduction in burden of annually preparing, submitting, and maintaining the records of the report on an annual basis.

Part 32 Expanding Distribution Pathways for Microsources

The NRC regulates the distribution of byproduct material for medical use under 10 CFR part 32. Specifically, § 32.72 governs the commercial distribution of radioactive drugs, while § 32.74 governs the distribution of sources and devices containing byproduct material. However, recent developments in clinical practice have highlighted the need to allow both distribution pathways to be available to microsources, which include radioactive microspheres used for intravascular brachytherapy. The proposed amendments to 10 CFR part 32 in this rulemaking would allow additional authorizations for the preparation and distribution of radioactive microspheres.

Microspheres are regulated by the FDA as medical devices and they are not considered radioactive drugs. As such, manufacturing, preparation and transfer of microsources is not addressed under § 32.72 and must be authorized under § 32.74, even though the radiation safety considerations between microsources and radioactive drugs are similar. This requirement has become a burden following the implementation of United States Pharmacopeia (USP) General Chapter <825>, which included standards for the preparation, compounding, dispensing, and repackaging for radioactive microspheres similar to radiopharmaceuticals.

The USP sets quality, purity, strength, and identity standards for medicines, food ingredients, and dietary supplements used in the United States. USP standards are enforceable by the FDA and State Boards of Pharmacy. As such, USP standards are widely adopted in healthcare and pharmaceutical practice. USP <825> requires that sterile radioactive microspheres be prepared in International Organization of Standardization (ISO) Class 5 environments if they are to be used more than one hour after puncture. To comply with these requirements and accommodate patient-specific treatment schedules, medical use licensees have increasingly relied on commercial radiopharmacies to prepare and distribute patient-ready doses of microspheres. As radiopharmacies historically focused their activities on radioactive drugs, they are licensed under § 32.72. However, the current regulatory framework does not authorize commercial radiopharmacies for preparing and distributing microspheres under § 32.72.

The proposed rule would revise § 32.72 to include microsources within its scope, which would allow commercial radiopharmacies that are licensed under this provision to prepare and distribute microspheres. In addition, the proposed rule would expand those who can use the § 32.72 pathway to any applicant who is legally authorized, under applicable Federal or State law, to manufacture, compound, prepare, or distribute radioactive drugs or medical devices to allow flexibility for future pathways allowed by states or the FDA to distribute radioactive drugs and medical devices safely.

The NRC is also proposing to revise § 32.74 to provide provisions specific to microsources, including microspheres. The revised language ensures clarity that licensees can use either § 32.72 or § 32.74 to distribute microsources. The amendments to § 32.74 also clarify that the regulation allows distribution to any licensee authorized to use the source or device under 10 CFR part 35 and does not limit distribution to specific types of medical facilities listed under specific subparts to avoid unnecessary limitations. A conforming change to § 30.32 would be made based on the changes in the structure of § 32.72.

These changes are intended to reduce regulatory burden and improve clarity for regulators and, radiopharmacy licensees, medical device manufacturing licensees, and medical licensees. By allowing both §§ 32.72 and 32.74 to serve as licensing pathways for the distribution of microsources, the NRC is allowing licensees to select the most appropriate regulatory framework based on their business model and operational needs. This flexibility supports compliance with USP <825>, enables timely access to microspheres for patient care, and maintains public health and safety.

Part 34 Reducing Anti-Competitive Barriers and Administrative Requirements for Industrial Radiography

The NRC's regulations in 10 CFR part 34 establish the specific requirements for industrial radiography. The proposed changes to 10 CFR part 34 in this rulemaking aim to provide greater flexibly in the use of codes and standards, clarify the two-person rule; and update prescriptive administrative requirements to allow for a more performance-based approach, while continuing to ensure the protection of public health and safety.

Current NRC regulations in § 34.20(a)(1) require that radiographic equipment meet the standards in ANSI N432–1980, ''Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography.'' ANSI N432 was incorporated into NRC regulations on January 10, 1990 (55 FR 843) because manufacturers of radiography equipment were not all consistently using ANSI N432, nor were they uniformly or fully implementing the performance criteria intended to improve radiation safety for workers. However, ANSI N432 has been superseded by ANSI N43.9–1991, ''For Gamma Radiography—Specifications for Design and Testing of Apparatus.'' Additionally, other applicable industry standards have also been developed. Pursuant to the SSDR program in § 32.210, radiographic exposure devices, source assemblies, and sealed sources are evaluated using accepted industry standards to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. The NRC is removing requirements that incorporate specific standards to stay current with the industry as these standards may become obsolete or superseded. The proposed rule would remove the prescriptive and outdated reference to ANSI N432–1980 and instead require that radiography devices, source assemblies, and sealed sources be evaluated and registered in the SSDR. Additionally, since § 34.20 also discusses associated equipment that is not evaluated under the SSDR, the proposed rule would also require that this equipment meets the manufacturers' specifications and instructions. Manufacturer specifications include design elements and criteria necessary for the safe function of the associated equipment. This change will conform § 34.20 with § 32.210 while continuing to ensure that radiography licensees use and maintain the radiography device, sealed source, and associated equipment in accordance with the industry standards and manufacturer requirements it was designed to meet. The removal of the incorporation by reference of an industry standard will also prevent this requirement from becoming superseded and needing to be revised in the future. Further § 34.20(a)(2) will remain to provide a pathway for licensees to use alternative standards on a case-by-case basis. Finally, NRC is proposing a conforming change to § 34.3 to define SSDR for 10 CFR part 34. These changes will ensure that radiation safety is maintained while reducing anti-competitive regulatory barriers and allowing for innovation in the design of radiography equipment.

On May 28, 1997, the NRC issued § 34.41(a) ''Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations,'' commonly called ''the two-person rule,'' which requires a second qualified individual (radiographer or radiographer's assistant) to be present during industrial radiography operations at temporary jobsites (TJS) (62 FR 28948). The purpose of the second individual is to provide immediate assistance when required and to prevent unauthorized entry into the restricted area.

Prior to 2021, the NRC had consistently interpreted § 34.41(a) to require both the radiographer and the second qualified individual to maintain direct observation when radiographic operations are being conducted at a TJS. Through operating experience, this interpretation was found to be unnecessary to protect public health and safety, and on June 1, 2021, the NRC reinterpreted the requirement (86 FR 29173).

Since 2021, NRC has interpreted § 34.41(a) such that the requirements contained in the sentence, ''[t]he additional qualified individual shall observe the operation and be capable of providing immediate assistance to prevent unauthorized entry'' are met if the second qualified individual is in sufficiently close proximity to the operation and sufficiently aware of the ongoing activities to be able to provide assistance or take charge when necessary and to prevent unauthorized entry. The second individual may perform other tasks nearby so long as they are cognizant of the site-specific circumstances when radiographic operations are in progress. In 2021, the NRC also determined that this interpretation makes § 34.41(a) consistent with the requirement in § 34.51 that at least one of the two individuals present at a TJS must ''maintain direct observation of the operation,'' the NRC discontinued planned rulemaking after determining that the reinterpretation resolved the issues raised in PRM–34–6 which requested that 10 CFR part 34 clarify requirements related to the responsibilities of the second individual required to be present during radiographic operations.

The proposed rule would combine the requirements in § 34.51 into § 34.41(a) to create a single, concise requirement regarding the availability and surveillance responsibilities of the qualified individuals performing industrial radiography at TJSs. This change seeks to eliminate ambiguity, allowing for technological innovation in the implementation of the requirement, all while maintaining the integrity of the performance requirements. Combining § 34.41 and § 34.51 into a single simplified requirement enhances regulatory clarity by plainly aligning the requirement with the reinterpretation from 2021.

Part 34 of 10 CFR currently contains obsolete and overly prescriptive administrative requirements dating from its last significant revision in 1997 (62 FR 28948). Many of these requirements are not consistent with the NRC's modern and performance-based approach to oversight. For example, the operational history of § 34.101(c), which requires notification when work activities at a TJS exceed 180 days, is unnecessary because the information is collected during routine inspections and does not provide value to the NRC's performance based oversight program. The proposed rule would also reduce administrative burden on licensees by reducing the record keeping requirements in § 34.89(b) to remove duplicative records and by eliminating the notification requirement in § 34.101(c) which required licensees to notify the appropriate NRC Regional Office prior to exceeding 180 days at a TJS in a calendar year. The notification requirement can be eliminated because it can be reviewed through the routine inspection program.

The proposed rule would align leak testing requirements in § 34.27(c) with the SSDR. The sealed source leak testing frequency in the SSDR is based on the specifications of the sealed source specific to the design of the device for which it is used. This proposed change could reduce administrative burden on radiography licensees while ensuring that radiation safety is maintained and the leak testing frequency used is specific to the source model.

The proposed changes would further streamline 10 CFR part 34 by removing the obsolete legacy requirements related to previous rules that are no longer applicable and that were put in place to allow legacy incorporation for certain requirements in §§ 34.13(b)(2), 34.27(e), 34.41(d), 34.43(a)(2),(h), and (i).

The proposed revisions to 10 CFR part 34 would affect industrial radiographic license holders. The changes would reduce the administrative burden on license holders and the changes to streamline and clarify which would enable greater comprehension of the rule and increased compliance. Additionally, the changes to § 34.20 would allow greater flexibility to industrial radiography equipment manufacturers by removing the overly prescriptive performance design criteria that the equipment must currently meet.

Part 39 Modernizing Well Logging Regulations

The NRC is proposing to streamline 10 CFR part 39 to by amending requirements related to instrument calibration intervals (§ 39.33(c)(1)), leakage testing for each sealed source (§ 39.35(c)(1)) and certain notification requirements.

Current NRC regulations in § 39.33(c)(1) require that the licensee shall have each radiation survey instrument calibrated at intervals not to exceed 6 months and after instrument servicing. The proposed rule would extend this frequency from 6 months to 12 months to be consistent with other regulations regarding the calibration of survey instruments found in 10 CFR parts 35 and 36. It is necessary that well logging licensees use equipment that has been calibrated to ensure accuracy of radiation emitted and associated radiation detection practices, however, this should be consistent with other regulations. This would ensure that radiation safety is maintained while decreasing administrative and financial burden on the licensee.

The NRC regulations in § 39.35(c)(1) require that each sealed source (except an energy compensation source (ECS)) must be tested for leakage at intervals not to exceed six months. However, other parts of this chapter allow for leak tests to be conducted at frequency outlined in the SSDR, which may list periods longer than six months. The proposed rule would align the leak testing provisions in other parts of NRC regulations and would be consistent with the intervals approved by the NRC or an Agreement State on the SSDR. It is necessary that well logging licensees ensure sealed sources are not leaking; however, this should be consistent with the source design specifications of the SSDR. This would ensure that radiation safety is maintained, and the leak testing frequency used is specific to the source model while reducing administrative and financial burden on the licensee.

Current NRC regulations in § 39.77(c)(1) require that the licensee shall notify the appropriate NRC Regional Office by telephone of the circumstances that resulted in the inability to retrieve the source and obtain NRC approval to implement abandonment procedures. These procedures are reviewed and approved by the NRC during the licensing process. The proposed rule would reduce administrative burden on applicants and licensees by eliminating

the notification requirement in § 39.77(c)(1). The notification requirement can be eliminated because it is not needed for the licensee to implement operating and emergency procedures for abandonment that have already been approved by the NRC during the licensing process. The NRC's approval is for the licensee to implement the procedures that were approved during licensing, which is unnecessary, because the NRC's approval at the time of notification does not change the previously approved procedures. The removal of § 39.77(c)(1) would eliminate the notification and duplicative approval process for implementing abandonment procedures.

Part 150 Modernizing Requirements for Agreement State Licensees in Part 150

The proposed changes 10 CFR part 150 concern (1) regulation of special nuclear material of low strategic significance (SNM–LSS), and (2) reciprocity, which allows the NRC to recognize Agreement State licenses in certain circumstances, and vice versa.

First, consistent with Section 274 of the AEA, Agreement States may assume regulatory authority over SNM in quantities not sufficient to form a critical mass, including SNM–LSS. SNM–LSS includes gram quantities of plutonium or uranium-233 or uranium-235, or certain combinations of the three. These materials are used in research or in the manufacture of certain radiation detectors. Currently, there are 10 Agreement State licensees that possess SNM of low strategic significance (SNM–LSS). While otherwise Agreement State licensees, the NRC reserved regulation over SNM–LSS under its common defense and security authority. Thus, Agreement State licensees possessing SNM–LSS must follow § 73.67 pursuant to § 150.14.

Prior to 2023, the NRC had not exercised any oversight over Agreement State licensees for compliance with § 73.67. On March 6, 2023, a Temporary Instruction (TI) 2800/044,''Assessment of Physical Protection Requirements under § 150.14 For Agreement State Licensee Processing, Using, or Transporting Special Nuclear Material of Low Strategic Significance,'' was issued to evaluate, through inspection, whether Agreement State licensees had adequate physical protection processes and procedures in place for the possession, use, and transport of SNM–LSS consistent with the requirements of § 73.67. The NRC inspectors identified, through TI 2800/044 inspections, that Agreement State licensees in possession of SNM–LSS store the material in secure areas where other radioactive materials are stored. Considering the low safety and security significance of SNM–LSS and the results of TI 2800/044 inspections, the NRC determined that security requirements in § 20.1801 ''Security of stored material'' and § 20.1802 ''Control of material not in storage'' are adequate to secure SNM–LSS.

The current regulatory approach for SNM–LSS Agreement State licensees means that these licensees are subject to oversight by both the NRC and their Agreement State regulator (NRC currently oversees physical protection of SNM–LSS and the Agreement State oversees control of radiation hazards associated with the SNM to ensure adequate protection of public health and safety). In addition, the NRC does not have a pathway to recover inspection costs from these Agreement State licensees and the additional cost for these inspections is shouldered by NRC licensees.

The proposed rule would delete § 150.14, which requires Agreement State licensees that possess SNM–LSS to meet the physical protection requirements in § 73.67. The deletion of § 150.14 would affect Agreement State licensees possessing SNM–LSS by removing the requirement to implement the physical protection requirements in § 73.67. Under this change, the NRC would no longer have oversight of SNM–LSS in Agreement States and the Agreement States would continue to maintain oversight of the security of this material under their current programs based on security requirements found in 10 CFR part 20. There would also be a minimal resource savings for the NRC by no longer having regulatory oversight of this requirement.

The proposed rule also addresses reciprocity, which is the NRC's recognition of Agreement State licenses for work performed in areas of NRC jurisdiction, without the licensee having to obtain a specific license from the NRC. Under reciprocity, the NRC grants a GL to Agreement State licensees for work in NRC jurisdiction for periods not exceeding 180 days in a calendar year (except for activities performed in offshore waters which does not have a time period limit). The provisions in § 150.20 require a specific license from an Agreement State as the basis for the GL to be granted. Areas of NRC jurisdiction include non-Agreement States, areas of exclusive Federal jurisdiction, and offshore waters. The term reciprocity is also used in Agreement States to identify Agreement State recognition of an NRC license and licenses from other Agreement States for work performed in their jurisdiction. Some types of activities conducted under reciprocity include radiography, portable gauge use, well logging, leak testing, and calibration.

Activities conducted by Agreement State licensees in an NRC jurisdiction must meet the GL provisions of § 150.20, ''Recognition of Agreement State Licenses.'' Pursuant to this provision, prior to engaging in licensed activities an agreement state licensee must provide an NRC Form 241 ''Report of Proposed Activities in Non-Agreement States,'' a copy of its Agreement State specific license, and the appropriate fee as prescribed in § 170.31. Currently, Agreement State licensees provide these materials at least 3 days before engaging in an activity for the first time in a calendar year. Additionally, Agreement State licensees must file an amended NRC Form 241 to request approval for changes in work locations, radioactive materials, or work activities different from the initial request. Work performed under reciprocity is limited to 180 days in any calendar year, except for offshore activities, which are authorized for an unlimited period in the year. The NRC has published guidance in NUREG–1556, Volume 19, ''Guidance for Agreement State Licensees About NRC Form 241 ''Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters.''

Between 2020 and 2024, the NRC annually processed on average 180 initial reciprocity filings and 1,386 amended reciprocity filings. Most initial reciprocity requests create a significant workload on NRC regional staff to review and approve the requests within the three-day time window. The majority of, if not all, reciprocity initial applications are approved. Additionally, there is an administrative burden on the licensee to ensure timely filing for initial reciprocity and ensure that amended forms are filed when required (*i.e.,* changes in work location, radioactive material, or different work activities).

The information collected on NRC Form 241 provides the NRC an opportunity for oversight including the conduct of inspections. The NRC conducts approximately 21 of these inspections each year. Each year, NRC staff processes hundreds of reciprocity amendments related to offshore work, mostly for changes in location. Due to logistical challenges and expense required to perform inspections offshore, the NRC has not performed

any inspection of offshore work in several years.

The NRC is proposing to revise § 150.20(b)(1) to reduce the notification time for submitting an initial reciprocity filling from three days before engaging in an activity to the day of the activity. The revision would also delete § 150.20(b)(1)(i)–(iii), which currently allows for submittals with less than three days for emergent reasons, as it would be superfluous. The proposed revisions to § 150.20(b)(1) would allow licensees greater flexibility in scheduling licensed activities that require reciprocity with minimal impact on public health and safety. This change would affect Agreement State licensees performing work in areas of exclusive Federal jurisdiction by reducing the administrative burden to file for reciprocity prior to conducting work activities. Specifically, for reciprocity submitted less than three days prior to engaging in the initial work activities, Agreement State licensees would no longer be required to provide additional justification regarding the emergent nature of the work.

For amended reciprocity filings pursuant to § 150.20(b)(2), the proposed revisions would remove the requirement that Agreement State licensees engaging in activities offshore amend the NRC Form 241 for changes in work locations. This proposed change would affect Agreement State licensees working in offshore waters by significantly decreasing the number of amended NRC Form 241s submitted. Correspondingly, this change would also lessen the administrative burden on NRC staff by reducing the number of NRC Form 241s that are required to be processed.

Finally, to allow SGLs from Agreement States to be recognized by the NRC for the purposes of reciprocity, the proposed rule would revise §§ 150.20(a)(1), 150.20(a)(2), 150.20(b), 150.20(b)(1), and 150.20(b)(5) to include SGLs from Agreement States in addition to specific licenses throughout the requirement. These changes would allow Agreement State licensees, that have been granted an SGL, to work in NRC jurisdiction for up to 180 days without obtaining a specific license or SGL from the NRC. This would ensure that SGLs are not precluded from the ability to use the provisions of § 150.20 which would ensure parity between businesses conducting similar licensed activities but operating under a standard general licensees or specific license.

V. Specific Requests for Comments

The NRC is seeking feedback from the public on the proposed rule. We are particularly interested in comments and supporting rationale from the public on the following:

- The NRC is seeking comments on how many persons that currently possess a specific license for portable gauge activities, fixed gauge activities, limited medical uses, analytical equipment uses, and in vitro testing would transition to a SGL that is described in the changes to 10 CFR part 31 subpart C. The NRC is also seeking comments on the costs and the benefits of the new SGL. Please provide a basis for your response.
- The NRC is seeking comments on possible impacts to small entities. The regulations in § 2.810, ''NRC size standards,'' provide specific size standards to determine whether a licensee qualifies as a small entity in its regulatory programs.
- As part of the wholesale review of regulations the NRC reviewed all reporting and notification requirements that reside within 10 CFR parts 30–39. The NRC is proposing changes to some of these requirements as part of this rulemaking. During the review, the NRC considered revising notification and reporting requirements in § 30.50(b)(2) to exclude the reporting for certain circumstances that fixed gauge licensees may encounter. This requirement currently requires a 24-hour notification and a 30-day written report for a variety of incidents including when a fixed gauge shutter is found to be inoperable and stuck in the open position. During the review, the NRC considered whether the reporting of fixed gauges with stuck shutters in the open position, when the open position is the normal operating mode, and the stuck position has been found by the licensee to pose no radiation hazard to workers, the public, or the environment was necessary. The NRC considered exploring whether it could issue a generic communication to exclude these events by reinterpreting what is meant in § 30.50(b)(2)(ii) by ''the equipment is required to be available and operable when it is disabled or fails to function.'' Alternatively, the NRC considered revising § 30.50 to provide the exclusion for these circumstances related to fixed gauges. Ultimately, the NRC determined that the impacts to the wide range of circumstances that are reported under § 30.50 warrants further review to ensure all consequences are understood. The NRC is seeking comments on whether inoperable fixed gauges that operate with open shutters but have shutters stuck in the open position, that pose no radiation hazard, warrant reporting and notification to the NRC. If reporting and notifications are warranted, the NRC is seeking comments on the appropriate timeline and content of the reports and notifications. Additionally, the NRC is seeking comments on what criteria, related to fixed gauges with stuck shutters, should be included to determine whether a hazard to the workers, the public, or the environment exists as a result of the stuck shutter. Please provide a basis for your response. Finally, the NRC is seeking comments on all event reporting and notification requirements in 10 CFR parts 30–34, 39, 40, and 150 related to the burden, content, and required timeframe associated with each report or notification. Please provide a basis for your response.

VI. Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, would not have a significant economic impact on a substantial number of small entities. Therefore, in accordance with section 605(b), the NRC is not preparing a regulatory flexibility certification analysis. This proposed rule would affect a small number of ''small entities'' as defined by the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810), but it would not be a significant impact.

Any small entity subject to this regulation that determines, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this opinion in a comment that indicates—

(a) The licensee's size and how the proposed regulation would impose a significant economic burden on the licensee as compared to the economic burden on a larger licensee;

(b) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities;

(c) The benefits that would accrue or the detriments that would be avoided if the proposed regulations were modified as suggested by the licensee;

(d) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group; and

(e) How the proposed regulation, as modified, would still adequately protect public health and safety.

Comments should be submitted as indicated under the **ADDRESSES** caption.

VII. Regulatory Analysis

A. Introduction

The NRC has prepared a draft regulatory analysis on this proposed rule. The analysis examines the costs and benefits of the alternatives considered by the NRC. The NRC has preliminarily determined that the proposed action in this rule is expected to reduce regulatory burden and generate cost savings for licensees, the NRC and the Agreement States, when compared to the no-action alternative. The NRC requests public comment on the draft regulatory analysis. Comments on the draft regulatory analysis may be submitted to the NRC as indicated under the **ADDRESSES** caption of this document.

B. Identification and Preliminary Analysis of Alternative Approaches

The NRC identified two alternatives for this action: (1) no action (*i.e.,* maintaining the status quo regulatory baseline), and (2) the proposed rulemaking to revise language for the licensing of byproduct material.

The assessment of total costs and benefits discussed previously leads the NRC to the conclusion that the proposed rule, if implemented, would result in quantifiable net cost savings for industry, the NRC and Agreement States. In addition, the NRC concludes that the rule provides nonquantified benefits of regulatory clarity and improved consistency in the regulatory program. The proposed rule is also responsive to stakeholder feedback and aligns with E.O. 14300.

VIII. Backfitting and Issue Finality

The NRC has determined that this proposed rule would not constitute backfitting as that term is defined in the NRC's backfitting provisions in §§ 50.109, 70.76, 72.62, and 76.76, all titled ''Backfitting,'' or affect the issue finality of an approval issued under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' The proposed amendments would not include any provisions that would impose new or modified requirements on existing licensees, applicants, or certificate holders that are within the scope of a backfitting or issue finality provision. The proposed changes would not inextricably affect activities of licensees that are within the scope of the backfitting or issue finality provisions. Additionally, 10 CFR part 70 licensees within the scope of § 70.76 would not be impacted by this proposed rule. Each of these licensees is already required to submit a site-specific financial assurance plan because their authorized possession limits already exceed the proposed table values. For these reasons, the proposed rule would not meet the definition of ''backfitting'' under § 50.109, § 70.76, § 72.62, or § 76.76, or affect the issue finality of an approval issued under 10 CFR part 52.

This proposed rule also includes the draft guidance documents described in section XIV, ''Availability of Guidance,'' These documents if finalized, would not constitute backfitting as defined in § 50.109, § 70.76, § 72.62, or § 76.76 or affect the issue finality of any approval issued under 10 CFR part 52 because the guidance would not inextricably affect activities of licensees that are within the scope of the backfitting or issue finality provisions. The guidance would not impose new or modified requirements on existing licensees, applicants, or certificate holders that are within the scope of a backfitting or issue finality provision.

IX. Cumulative Effects of Regulation

The NRC seeks to minimize potential negative consequences resulting from the cumulative effects of regulation (CER). The NRC believes that the de-regulatory impacts of this rulemaking activity are unlikely to cause implementation challenges for stakeholders. In addition, during the pendency of this rulemaking, the NRC is deprioritizing issuance of regulatory actions that might influence the implementation date for the new rule requirements (*e.g.,* orders, generic communications, license amendment requests, and inspection findings of a generic nature).

To fully understand any potential CER implications that could result from this rulemaking, the NRC is asking the following questions. Response to these questions is voluntary and any input will be considered during development of the final rule.

1. The NRC is proposing an effective date that will be 30 days after the date of publication of a final rule. Does this provide sufficient time to implement the proposed requirements? Please provide a rationale for your response.

2. Are there unintended consequences related to this rulemaking and how should they be addressed? Please provide a rationale for your response.

3. Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule.

X. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31883). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XI. Environmental Assessment

A. Introduction

The NRC has prepared this environmental assessment (EA) of the proposed rule amending regulations for byproduct, source, and special nuclear material use to determine the significance of the environmental effects of the proposed agency action in accordance with the National Environmental Policy Act of 1969, as amended (NEPA) and the NRC's NEPA implementing regulations in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.'' As explained below, the NRC has preliminarily determined that the proposed agency action to modernize the NRC regulations for byproduct, source, and special nuclear material use would have no significant effect on the quality of the human environment.

B. Environmental Impacts of the Proposed Action

The proposed action would amend multiple NRC regulations in 10 CFR parts 30, 31, 32, 34, 39, 40, 70, and 150 regarding licensed material use. Conforming changes would also be made to guidance consistent with the changes to regulations. Table B–1 lists the sections of the regulations that would be updated and the affected guidance documents.

TABLE B–1 REGULATION UNDER THE PROPOSED MODERNIZING NRC REGULATIONS FOR BYPRODUCT MATERIAL USE

Rulemaking	Regulations	Guidance
Modernizing NRC Regulations for Byproduct Material Use.	30.4, 30.6, 30.32, 30.34, 30.35, 30.41, Appendix B to Part 30, 31.5, 31.11, 31.13 (new), 31.14 (new), 31.15 (new), 31.16 (new), 31.17 (new), 31.18 (new), 32.12, 32.16, 32.20, 32.25, 32.29, 32.32, 32.72, 32.74, 34.3, 34.13, 34.20, 34.23, 34.27, 34.33, 34.41, 34.43, 34.51, 34.89, 34.101, 39.33, 39.35, 39.77, 40.53, 70.25, 150.14, 150.20	Interim Staff Guidance.

Conforming changes are administrative actions with no physical environmental effect and provide for the appropriate administrative and regulatory framework for byproduct material use under 10 CFR. An example would be adding a reference to a newly created subsection in an existing regulation. Most of the amendments to NRC regulations in the proposed rule occur within the affected regulation. The proposed rule includes conforming changes to NRC regulations in 10 CFR parts 30, 32, and 34.

B.1 Rule Amendments Addressed Under Categorical Exclusion

The NRC has determined that some of the changes to the regulations identified in this proposed rule meet the criteria for categorical exclusion under § 51.22, ''Categorical Exclusions.'' Categorical exclusions provide a mechanism to identify Federal actions that normally do not have a significant environmental effect on the human environment and for which neither an EA nor environmental impact statement is normally required. This ensures that resources are not expended on the environmental analysis of proposed actions that do not present the potential for significant environmental effects. Rule amendments with applicable categorical exclusions are presented in Table B–2 below and no further NEPA analysis is required.

These proposed rule amendments belong to categories of actions which the Commission, by rule or regulation, has declared to be a categorical exclusion, after first finding that the category of actions do not individually or cumulatively have a significant effect on the human environment. In reviewing list of regulations in Table B–1, the NRC staff have determined that several of the rule amendments under consideration are actions eligible for categorical exclusion under § 51.22(a)(1) or § 51.22(a)(3). The following rulemaking actions meet the criterion for categorical exclusion under § 51.22(a)(1) or § 51.22(a)(3):

TABLE B–2 RULE AMENDMENTS COVERED BY CATEGORICAL EXCLUSION

Rule amendments	Categorical Exclusion	Reason
30.4; 30.6; 30.32; 30.41 31.5; 31 subparts A, B, D and E. 34.3, 34.13; 34.20; 34.23; 34.27; 34.33; 34.43; 34.89; 34.101; 39.33; 39.35; 39.77.	§ 51.22(a)(1)	Actions that are administrative, procedural, or solely financial in nature, including examples (iv) and (vi). Example (iv): issuance of or changes to administrative procedures or requirements. Example (vi): the proposed amendments are also corrective or of a minor or nonpolicy nature, and do not substantially modify existing regulations.
30.34, 30.35; 32.12; 32.16; 32.20; 32.25; 32.29; 32.32; 40.53; 70.25.	§ 51.22(a)(1)	Actions that are administrative, procedural, or solely financial in nature, including Example (ii): issuance of or changes to recordkeeping or reporting requirements.

These proposed rule amendments clarify NRC regulations and would not change radiation protection and emergency preparedness requirements while continuing to provide reasonable assurance of adequate protection of public health and safety.

B.2 Rule Amendments Requiring Environmental Assessment

The NRC also evaluated rule amendments that have the potential to affect the human environment and determined that the proposed agency action (rulemaking) would not have a significant environmental effect. These rule amendments would clarify NRC regulations, would not change existing radiation protection and emergency preparedness requirements or overall risk, would continue to provide reasonable assurance of adequate protection of public health and safety, and would result in no new or different environmental effects. The following table presents the basis for why these proposed rule amendments would have no significant environmental effects.

TABLE B–3 BASIS FOR NO SIGNIFICANT ENVIRONMENTAL EFFECTS DETERMINATION FOR RULE AMENDMENTS NOT COVERED BY A CATEGORICAL EXCLUSION

Rule amendments	Basis for no significant environmental effects
Part 30, Appendix B	These proposed amendments would replace the current values in appendix B with applicable values from the table in appendix C, ''Quantities of Licensed Material Requiring Labeling,'' to 10 CFR part 20, ''Standards for Protection against Radiation.'' They also add radionuclides not currently listed in appendix B to 10 CFR part 30, including radionuclides associated with industrial technologies and current and emerging medical uses. The proposed changes would also remove all radionuclides with a half-life of 120 days or less from the appendix, since these radionuclides are not considered when developing decommissioning financial assurance, and amends the title of the table to ''Quantities of Licensed Material Used to Assess Financial Assurance for Decommissioning,'' to more accurately reflect its current use for financial assurance during decommissioning. These changes will either reduce or not affect the amount of DFA required for licensees, depending on the mixture of radionuclides the licensee possesses and would have no different environmental effects. Thus, this regulatory change would have no significant effect on the quality of the human environment.
31.11	Amendments would allow entities to handle vials for in vitro testing with higher activity under a general license. This change would align limits for carbon-14, hydrogen-3, selenium-75, and cobalt-57 with the exempt quantity limits in 10 CFR part 30 and labelling requirements in appendix C to 10 CFR part 20. The limits in § 31.11 have not been updated since their initial issuance in 1968 and the amendments would bring § 31.11 in step with current regulatory limits in 10 CFR parts 20 and 30. Given that the amendments would align with other existing requirements in 10 CFR parts 20 and 30, the amendments would have no significantly different environmental effects than those evaluated for 10 CFR part 20, and, thus, would have no significant effect on the quality of the human environment.
Subpart C—Standard General Licenses: New regulations 31.13 through 31.18.	The amendments to this subpart would establish a new regulatory program and grant standard general licenses in accordance with specific conditions. Each technology would have its own standard general license requirements codified in separate regulations, including: • § 31.14: Certain Fixed Gauging; • § 31.15: Portable Gauging; • § 31.16: Certain Medical Uses; • § 31.17: Certain Analytical Equipment Including Electron Capture Detectors, X-Ray Fluorescence Devices, and Ion Generators; and • § 31.18: Certain In Vitro Testing. These amendments propose a new class of general licenses for some low risk standardized operations that are currently specifically licensed, and all of the specifically licensed activities are currently categorically excluded. Because the NRC previously concluded that these activities do not individually or cumulatively have a significant effect on the human environment, no additional analysis is needed. Additionally, these amendments do not authorize any activities not included in 10 CFR part 30.
32.72; 32.74	The proposed amendments to § 32.72, commercial distribution of radioactive drugs for medical use under 10 CFR part 35, would be expanded to include microsources (e.g., microspheres) allowing radiopharmacies to prepare and distribute these materials. Proposed amendments would also provide flexibility for future distribution authorized by the U.S. Food and Drug Administration (FDA) or State regulatory bodies. In addition, proposed amendments to § 32.74 would clarify the distribution of sources and devices containing byproduct material. These two changes would ensure that manufacturers and commercial radiopharmacies can be licensed to distribute microsources in a manner consistent with NRC safety requirements and FDA classifications, while minimizing burden on radiopharmacy and medical use licensees. These changes are administrative and procedural and would not authorize any site-specific action on the part of the NRC or licensee. Licensees and applicants would need to request and receive separate regulatory approval before preparing and distributing microsources. Consequently, this rulemaking provides the basis for any procedure granting the license but does not, by its own operation, provide a license for preparation or distribution activities, but rather applicants must comply with the relevant NRC or Agreement State regulations before they can receive a license. Therefore, this rulemaking will not result in any physical impacts to the environment, and the NRC has determined that the action would result in no significant environmental impacts.
34.41; 34.51	These proposed amendments would combine the requirements in § 34.51 with requirements in § 34.41(a), commonly called ''the two-person rule,'' ''Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations'' and eliminate § 34.51. The regulation requires a second qualified individual (radiographer or radiographer's assistant) to be present during industrial radiography operations at temporary jobsites. The revision eliminates ambiguity, allowing for technological innovation in the implementation of the requirement, all while maintaining the integrity of the performance requirements. This action does not alter any the substantive activities under § 34.41(a), and would have no significantly different environmental impacts than those evaluated for § 34.41(a), and, thus, would have no significant effect on the quality of the human environment.

These proposed rule amendments would modernize existing NRC regulations while ensuring the continued safe, effective, and efficient use of byproduct material to provide reasonable assurance of adequate protection of public health and safety. As noted in Table B–3, these amendments either consist of administrative and procedural changes, or would have no significantly different environmental effects than those in the current regulatory framework. The table also provides rationale supporting the conclusion that these proposed rule amendments would not result in any significant environmental effects.

C. Summary of the Environmental Impacts of the Proposed Action

Implementation of the proposed rule would result in no physical changes to the environment, and, therefore, the NRC has determined that this proposed agency action would not have a significant effect on the quality of the human environment. Proposed rule amendments include changes that: (1) are administrative in application and matters of procedure, (2) clarify record keeping and reporting requirements, and (3) would provide an equivalent level of safety and security as current NRC regulations.

In addition, the proposed rule would not affect any threatened or endangered

species or historic properties, as no physical changes to the human environment would occur as a result of this proposed agency action. Accordingly, the NRC finds that the proposed rulemaking would have no significant environmental impact.

D. Environmental Impacts of the Alternative to the Proposed Agency Action

Under the no-action alternative (*i.e.,* the status quo), NRC regulations would remain unchanged. As stated in section B of this draft EA, the proposed rule would not have a significant effect on the quality of the human environment. Therefore, the no action alternative and the proposed agency action (*i.e.,* proposed rulemaking) would have the same environmental effect, although there would be costs attributable to reviewing the environmental effects of exemption and license amendment requests under the no action alternative. Licensees would continue to comply with existing NRC regulations or request regulatory relief (exemption) from the regulations. The NRC would continue to evaluate the environmental effects of exemption and license amendment requests. The averted costs (benefits) of the rulemaking would not occur. The Regulatory Analysis for the proposed rule provides information about the costs and benefits of the no action alternative and the proposed agency action (ADAMS Accession No. ML26125A393).

E. Agencies and Persons Consulted

The NRC developed the proposed rule and is requesting public comment on this draft EA. The agency will consider comments received on the docket as it develops the final rule and the final EA. The NRC will issue the final EA when it publishes the final rule. The proposed rule is one step in the rulemaking process.

As discussed in section B, the proposed rule provisions would not have a significant effect on the quality of the human environment. For this reason, the proposed rulemaking would not impact threatened or endangered species or critical habitat, and the NRC has determined that section 7 consultation under the Endangered Species Act of 1973, as amended, is not necessary. The proposed regulatory changes do not involve any ground disturbing activities or visual effects that would adversely affect historic properties. Therefore, the NRC has determined that consultation is not required under section 106 of the National Historic Preservation Act of 1966, as amended.

F. Draft Finding of No Significant Environmental Impacts

The NRC has prepared this EA to determine the environmental effects of the proposed agency action (*i.e.,* a rulemaking to update NRC regulations). Proposed rule amendments are primarily administrative or procedural in nature and thus would not have any physical environmental effect. As explained in the EA, the NRC has determined the proposed rulemaking would not change radiation protection and emergency preparedness requirements or overall risk, would continue to provide reasonable assurance of adequate protection of public health and safety, and would result in no new or different environmental effects. Therefore, the NRC concludes that the proposed regulatory changes would not have a significant effect on the quality of the human environment. Based on this conclusion, the NRC finds the proposed agency action would have no significant environmental impact. Accordingly, the NRC has determined there is no need to prepare an environmental impact statement.

Concurrent with the publication of this proposed rule, the NRC has sent a copy of the draft EA and this proposed rule to every State Liaison Officer and has requested comments.

XII. Paperwork Reduction Act Statement

This proposed rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the information collections.

Type of submission: New.

The title of the information collection: Modernizing NRC Regulations for Byproduct Material Use.

The form number if applicable: NRC Forms 241, 313, 483, and 1003.

How often the collection is required or requested: Once, on occasion, and annually.

Who will be required or asked to respond: Applicants and licensees licensed to use byproduct, source, and special material.

An estimate of the number of annual responses:

10 CFR part 30: 570 (423 reporting responses + 147 recordkeepers)
10 CFR part 31: 1,449 (354 reporting responses + 1,095 recordkeepers)
10 CFR part 32: −109 (−109 reporting responses + 0 recordkeepers)
10 CFR part 34: −577 (−29 reporting responses + −548 recordkeepers)
10 CFR part 39: −8 (−8 reporting responses + 0 recordkeepers)
10 CFR part 40: −27 (−27 reporting responses + 0 recordkeepers)
NRC Form 241: −425 (−425 reporting responses + 0 recordkeepers)
NRC Form 313: −398 (−398 reporting responses + 0 recordkeepers)
NRC Form 483: 60 (60 reporting responses + 0 recordkeepers)
NRC Form 1003: 1,289 (1,289 reporting responses + 0 recordkeepers)
Total: 2,221 (1,528 reporting responses + 693 recordkeepers)

The estimated number of annual respondents:

10 CFR part 30: 423 respondents
10 CFR part 31: 1,095 respondents
10 CFR part 32: −109 respondents
10 CFR part 34: −548 respondents
10 CFR part 39: −2 respondents
10 CFR part 40: −27 respondents
NRC Form 241: −25 respondents
NRC Form 313: −398 respondents
Form 483: 60 respondents
NRC Form 1003: 398 respondents
Total: 897 unique respondents to the requirements in this proposed rule

An estimate of the total number of hours needed annually to comply with the information collection requirement or request:

10 CFR part 30: 23,736.6 (23,590 reporting + 146.6 recordkeeping)
10 CFR part 31: 1,490.3 (118.55 reporting + 1,371.8 recordkeeping)
10 CFR part 32: −34.55 (−34.5 reporting + 0 recordkeeping)
10 CFR part 34 −288.5 (−14.5 reporting + –274 recordkeeping)
10 CFR part 39: −4 (−4 reporting + 0 recordkeeping)
10 CFR part 40: −13.5 (−13.5 reporting + 0 recordkeeping)
NRC Form 241: −106.3 (−106.3 reporting + 0 recordkeeping)
NRC Form 313: −1,711.4 (−1,711.4 reporting + 0 recordkeeping)
NRC Form 483: −10.2 (−10.2 reporting + 0 recordkeeping)
NRC Form 1003: 881.55 (881.5 reporting + 0 recordkeeping)
Total: 23,960.4 (22,716.2 reporting + 1,244.4 recordkeeping)

Abstract: The NRC is proposing to amend its regulations to modernize the safe, effective, and efficient use of byproduct, source, and special nuclear material. This action would reduce licensing burden and the need for exemptions from existing regulations; address other deregulatory issues deemed relevant by the NRC; and support the NRC's Principles of Good Regulation, including openness, clarity, and reliability. This effort is consistent with, and implements direction in, the Accelerating Deployment of Versatile,

Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act), and recently issued E.O. 14300, ''Ordering the Reform of the Nuclear Regulatory Commission.''

The proposed rule covers a wide range of topics, including the following that would result in a reduction in recordkeeping and reporting requirements:

- Establishing a low burden class of standard GLs.
- Revising the decommissioning financial assurance tables.
- Addressing anti-competitive barriers.
- Reducing reporting of distribution to exempt persons.
- Removing or modifying redundant and unnecessary regulations.
- Reducing the burden for filing amended NRC Form 241's for work activities conducted in offshore waters.

This information collection includes burden reduction associated with revised information collection in 10 CFR parts 30, 31, 32, 34, 39, 40, and Forms 241, 483, and 313. It also includes burden associated with new information collection in proposed 10 CFR part 31 and proposed NRC Form 1003 that would create a low burden licensing option for licensees currently licensed under 10 CFR part 30 who use NRC Form 313.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility? Please explain your response.
2. Is the estimate of the burden of the proposed information collection accurate? Please explain your response.
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected? Please explain your response.
4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the Office of Management and Budget (OMB) clearance package and proposed rule are available in the ''Availability of Documents'' section of this document or may be viewed free of charge by contacting the NRC's Public Document Room reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* You may obtain information and comment on submissions related to the OMB clearance package by searching on *https://www.regulations.gov* under Docket ID NRC–2025–1205.

You may submit comments on any aspect of these proposed information collection(s), including suggestions for reducing the burden and on the above issues, by the following method:

Federal rulemaking website: Go to *https://www.regulations.gov* and search for Docket ID NRC–2025–1205.

Submit comments by June 17, 2026. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XIII. Coordination With NRC Agreement States

On September 3, 2025, the NRC held a Government-to-Government meeting with the OAS to discuss this rulemaking. The rulemaking working group that prepared this proposed rule also included representatives from OAS. Comments from the Agreement States were taken into consideration during the development of this proposed rule.

XIV. Compatibility of Agreement State Regulations

On the basis of the ''Agreement State Program Policy Statement'' approved by the Commission on October 2, 2017, and published in the **Federal Register** (82 FR 48535; October 18, 2017), NRC program elements can be placed into six categories (A, B, C, D, NRC, or health and safety (H&S)) to form the basis for evaluating and classifying the program elements. Under the Policy Statement, a program element means any component or function of a radiation control regulatory program, including regulations and other legally binding requirements imposed on regulated persons, which contributes to implementation of that program.

Compatibility Category A are those program elements that include basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. Compatibility Category A program elements adopted by an Agreement State should be essentially identical to those of the NRC to provide uniformity in the regulation of agreement material on a nationwide basis.

Compatibility Category B pertains to a limited number of program elements that cross jurisdictional boundaries and should be addressed to ensure uniformity of regulation on a nationwide basis. For Compatibility Category B, the Agreement State program element shall be essentially identical to that of NRC.

Compatibility Category C are those program elements that are important for an Agreement State to have in order to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State program shall embody the essential objectives of the Category C program elements. Under Category C, Agreement State program elements may be more restrictive than NRC program elements; however, they should not be so restrictive as to prohibit a practice authorized by the AEA, as amended, and in the national interest without an adequate public health and safety or environmental basis related to radiation protection.

Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, above, and are not required to be adopted by Agreement States for purposes of compatibility. An Agreement State has the flexibility to adopt and implement program elements within the State's jurisdiction that are not addressed by the NRC or that are not required for compatibility (*i.e.,* Compatibility Category D). However, such program elements of an Agreement State relating to agreement material shall (1) not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis; (2) not preclude a practice authorized by the AEA and in the national interest; and (3) not preclude the ability of the NRC to evaluate the effectiveness of Agreement State programs for agreement material with respect to protection of public health and safety.

Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the AEA, or provisions of 10 CFR. The NRC maintains regulatory authority over these program elements and the Agreement States must not adopt these NRC program elements. However, an Agreement State may inform its licensees of these NRC requirements through a mechanism under the State's administrative procedure laws, as long

as the State adopts these provisions solely for the purposes of notification, and does not exercise any regulatory authority as a result.

Category H&S program elements embody the basic health and safety aspects of the NRC's program elements. Although H&S program elements are not required for purposes of compatibility, they do have particular health and safety significance. The Agreement State must adopt the essential objectives of such program elements to maintain an adequate program.

This proposed rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. In this proposed rule, the NRC is not proposing to change the compatibility categories for requirements that are being amended. Therefore, for any requirements that are currently designated as Compatibility A or B, States would have to amend their rules to be essentially identical to the amended rule language.

However, for requirements that are designated as Compatibility C or Category H&S, States may not necessarily have to revise their rules so long as their current rule meets the essential objective for the amended requirement. For instance, the essential objective for § 150.20, is for Agreement States to provide reciprocal recognition of a specific license issued by the NRC or another Agreement State. However, proposed changes to § 150.20 include permitting SGLs to be used for the basis of reciprocal recognition. The NRC is proposing that the Compatibility Category of § 150.20 remain Category C, but to continue to meet the essential objective for the amended requirement, all Agreement States would be required to provide reciprocal recognition of a specific license or SGL issued by the NRC or another Agreement State. The State would have flexibility in the administration and requirements for reciprocity and would not need to revise their current program to remain compatible with the proposed revision to § 150.20.

The NRC is also proposing to remove requirements in §§ 34.20(d) and (e), 34.41(d), 34.43(a)(2), 34.43(h) and (i), 34.51, 34.101(c), and 39.77(c)(1). Except for 34.20(e), these requirements pertain to grandfathering and duplicative requirements and, as such, Agreement States are not required to also remove those regulations; Agreement States keeping their equivalent to the listed regulations (except for § 34.20(e)) would not lead to a disorderly pattern of regulation on a nationwide basis. However, Agreement States should remove their equivalent to § 34.20(e) to remove superseded standards and requirements. Failure to remove this would result in gaps and conflicts between programs in the National Materials Program that would negatively impact the uniformity of regulation on a nationwide basis because only radiographic equipment that meets the appropriate standards and requirements can used by licensees.

In developing the new SGL pathway, the NRC recognizes that Agreement States may not want to adopt the new subpart C of 10 CFR part 31, and it would therefore not be required for purposes of compatibility. For States that choose to adopt this pathway, some of the requirements would be required for either compatibility or H&S purposes. To ensure that transferors of devices and byproduct material are permitted to transfer materials to an SGL, the requirement in § 30.41(d)(1) is being revised.

The NRC is proposing that the Compatibility Category of § 30.41 remain Category C, but the NRC is proposing to clarify that to meet the essential objective for the amended requirement, all Agreement States must ensure that a validated SGL is an acceptable method of verification for § 30.41(c). Since a validated SGL is a verification method for transferring byproduct material under § 30.41(d), the requirement in § 31.13(a)(2), regarding issuing the validated SGL, is proposed to be designated as Compatibility Category C for Agreement States that adopt the SGL pathway. To meet the essential objective for § 31.13(a)(2), an Agreement State would need to issue a document validating an SGL. The SGL pathway codifies the minimum legally binding requirements needed to ensure health and safety that are required to obtain a specific license into the regulations, and it is therefore necessary that the State meet the essential objective for those requirements that have been designated as Compatibility Category C.

Provisions specifying the specific sealed sources and devices that are permitted under the SGL pathway are based on the SSDR use codes and have a proposed designation of Compatibility Category B since there is need for consistency across jurisdictions when using SSDRs for licensing purposes. The SGL for Certain Medical Uses includes an exhaustive list of the radionuclides authorized pursuant to 31.16(a)(2). Because 31.16(a)(2) is proposed to be designated Compatibility Category C, Agreement States would have the flexibility to permit other radionuclides than those authorized under the SGL to be used. However, authorizing additional radionuclides such as PET or generators other than Molybdenum-99/technetium-99m generators would not meet the essential objective for this requirement as these radionuclides or uses require additional licensing requirements to ensure an adequate level of safety. Administrative requirements, such as recordkeeping, are not required for purposes of compatibility and would be Compatibility Category D.

The proposed compatibility (A, B, C, D, and NRC) and adequacy (H&S) categories are designated in the following table.

ADEQUACY AND COMPATIBILITY TABLE

Section	Change	Subject	Compatibility	
			Existing	New
Part 30				
30.4	Amend	Definitions—Consortium	C	C.
30.4	Remove	Definitions—Physician	D.	
30.4	Amend	Definitions—Principal activities	D	D.
30.6(b)(1)	Amend	Communications	D	D.
30.32(j)(2)	Amend	Application for specific licenses	B	B.

ADEQUACY AND COMPATIBILITY TABLE—Continued

Section	Change	Subject	Compatibility	
			Existing	New
30.34(h)(1)	Amend	Terms and conditions of licenses	H&S	H&S. Note—the reference to 10 CFR 31 subpart C should only be included by States that adopt Standard General Licenses.
30.35(g)	Amend	Financial assurance and recordkeeping for decommissioning.	H&S	H&S. Note—the reference to 10 CFR 31 subpart C should only be included by States that adopt Standard General Licenses.
30.41(d)(1)	Amend	Transfer of byproduct material	C	C.
Appendix B	Amend	Appendix B—Quantities of Licensed Material Used to Assess Financial Assurance for Decommissioning.	B	B.
Part 31				
31.5(c)(14)	Amend	Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.	C	C.
31.5(c)(15)	Amend	Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.	C	C.
31.11(a)(3), (4), (6), & (8).	Amend	General license for use of byproduct material for certain in vitro clinical or laboratory testing.	D	D.
31.13(a) & (b), except (a)(2).	New	Standard General License Requirements		D.
31.13(a)(2)	New	Requirements		C—for States that authorize Standard General Licenses. D—for States who don't.
31.13(c) & (d)	New	Standard General License Requirements		C—for States that authorize Standard General Licenses. D—for States who don't.
31.13(e)	New	Standard General License Requirements		NRC.
31.13(f)–(h)	New	Standard General License Requirements		H&S—for States that authorize Standard General Licenses. D—for States who don't.
31.14 except (a)(2), (c)(2)(ii), (c)(3)(ii), (c)(6)(i), (c)(6)(iii), (c)(7)(ii), (c)(8)(ii), (c)(9)(i) & (c)(10)(ii).	New	Standard General License for Certain Fixed Gauging.		C—for States that authorize Standard General Licenses. D—for States who don't. Note—States should not incorporate references to Federal Government agencies.
31.14(a)(2)	New	Standard General License for Certain Fixed Gauging.		B—for States that authorize Standard General Licenses. D—for States who don't.
31.14(c)(2)(ii), (c)(3)(ii), (c)(6)(iii), (c)(7)(ii), (c)(8)(ii), (c)(9)(i) & (c)(10)(ii).	New	Standard General License for Certain Fixed Gauging.		D.
31.14(c)(6)(i)	New	Standard General License for Certain Fixed Gauging.		H&S
31.15 except (a)(2), (a)(3)(iii), (c)(2)(ii), (c)(3)(ii), (c)(5)(iii), (c)(7)(ii), (c)(8)(i).	New	Standard General License for Portable Gauging		C—for States that authorize Standard General Licenses. D—for States who don't. Note—States should not incorporate references to Federal Government. Reference to NRC Form 1003 is Compatibility D.
31.15(a)(2)	New	Standard General License for Portable Gauging		B—for States that authorize Standard General Licenses. D—for States who don't.
31.15(a)(3)(iii), (c)(2)(ii), (c)(3)(ii), (c)(5)(iii), (c)(7)(ii), (c)(8)(i).	New	Standard General License for Portable Gauging		D.

ADEQUACY AND COMPATIBILITY TABLE—Continued

Section	Change	Subject	Compatibility	
			Existing	New
31.16 except (c)(1)(iii), (c)(2)(iii), (c)(4)(iii), (c)(5)(iii), (c)(6)(iv).	New	Standard General License for Certain Medical Uses.		C—for States that authorize Standard General Licenses. D—for States who don't. Note—States should not incorporate references to Federal Government.
31.16(c)(1)(iii), (c)(2)(iii), (c)(4)(iii), (c)(5)(iii), (c)(6)(iv).	New	Standard General License for Certain Medical Uses.		D.
31.17 except (a)(2), (a)(3)(iii), (c)(2)(ii), (c)(4)(ii), (c)(5)(i) & (c)(6)(ii).	New	Standard General License for Certain Analytical Equipment Including Electron Capture Detectors, X-Ray Fluorescence Devices, and Ion Generators.		C—for States that authorize Standard General Licenses. D—for States who don't. Note—States should not incorporate references to Federal Government. Reference to NRC Form 1003 is Compatibility D.
31.17(a)(2)	New	Standard General License for Certain Analytical Equipment Including Electron Capture Detectors, X-Ray Fluorescence Devices, and Ion Generators.		B—for States that authorize Standard General Licenses. D—for States who don't.
31.17(a)(3)(iii), (c)(2)(ii), (c)(4)(ii), (c)(5)(i) & (c)(6)(ii).	New	Standard General License for Certain Analytical Equipment Including Electron Capture Detectors, X-Ray Fluorescence Devices, and Ion Generators.		D.
31.18 except (c)(1)(ii), (c)(2)(ii), (c)(4)(iii), (c)(5)(iii), (c)(6)(ii)–(iii).	New	Standard General License for Certain In Vitro Testing.		C—for States that authorize Standard General Licenses. D—for States who don't.
31.18 (c)(1)(ii), (c)(2)(ii), (c)(4)(iii), (c)(5)(iii), (c)(6)(ii)–(iii).	New	Standard General License for Certain In Vitro Testing.		D.
Part 32				
32.12	Amend	Same: Records and material transfer reports	NRC	NRC.
32.16	Amend	Certain items containing byproduct material: Records and reports of transfer.	NRC	NRC.
32.20	Amend	Same: Records and material transfer reports	NRC	NRC.
32.25	Amend	Conditions of licenses issued under§ 32.22: Quality control, labeling, and reports of transfer.	NRC	NRC.
32.29	Amend	Conditions of licenses issued under§ 32.26: Quality control, labeling, and reports of transfer.	NRC	NRC.
32.32	Amend	Conditions of licenses issued under§ 32.30: Quality control, labeling, and reports of transfer.	NRC	NRC.
32.72	Amend	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.	B	B.
32.74	Amend	Manufacture and distribution of sources or devices containing byproduct material for medical use.	B	B.
Part 34				
34.3	New	Definitions—Sealed Source and Device Registry.		[D].
34.13	Amend	Specific license for industrial radiography	C	C.
34.20(a)(1) & (c)	Amend	Performance requirements for industrial radiography equipment.	B	B.
34.20(a)(2)	Amend	Performance requirements for industrial radiography equipment.	D	D.
34.20(d) & (e)	Remove	Performance requirements for industrial radiography equipment.	B.	
34.23	Amend	Locking of radiographic exposure devices, storage containers and source changers.	B	B.
34.27(c)(1) & (e)	Amend	Leak testing and replacement of sealed sources	C	C.
34.33	Amend	Permanent radiographic installations	H&S	H&S.

ADEQUACY AND COMPATIBILITY TABLE—Continued

Section	Change	Subject	Compatibility	
			Existing	New
34.41(a)	Amend	Conducting industrial radiographic operations	C	C.
34.41(d)	Remove	Conducting industrial radiographic operations	D.	
34.43(a)(1)	Amend	Training	B	B.
34.43(a)(2)	Remove	Training	D.	
34.43(h) & (i)	Remove	Training	B.	
34.51	Remove	Surveillance	C	Note—requirement moved to 34.41(a).
34.89(b)	Amend	Location of documents and records	C	C.
34.101(c)	Remove	Notifications	C.	
Part 39				
39.33(c)	Amend	Radiation detection instruments	C	C.
39.35(c)	Amend	Leak testing of sealed sources	C	C.
39.77(c)(1)	Remove	Notification of incidents: abandonment procedures for irretrievable sources.	C.	
Part 40				
40.53(c)	Amend	Conditions for licenses issued for initial transfer of certain items containing source material: Quality control, labeling, and records.	NRC	NRC.
Part 70				
70.25(a)(2)	Amend	Financial Assurance and Recordkeeping for Decommissioning.	NRC	NRC.
70.25(b)	Amend	Financial Assurance and Recordkeeping for Decommissioning.	H&S	H&S.
Part 150				
150.14	Remove	Commission regulatory authority for physical protection..	NRC.	
150.20	Amend	Recognition of Agreement State licenses.	C	C. Note—States should not incorporate references to offshore waters.

Please Note: The bracket ''[]'' around a compatibility category designation means that the section may have been adopted elsewhere in a State's rules and it is not necessary to adopt it again.

XV. Coordination With the Advisory Committee on the Medical Uses of Isotopes

The ACMUI established a subcommittee to review and comment on the draft proposed rule. The subcommittee will make its recommendations to the full committee on this proposed rule at a publicly held teleconference during the public comment period.

XVI. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. The NRC's goals in amending these regulations are to modernize the safe, effective, and efficient use of byproduct material. This action would reduce licensing burden and the need for exemptions from existing regulations and address other deregulatory issues deemed relevant by the NRC. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XVII. Availability of Guidance

The NRC expects to update NUREG–1556 series ''Consolidated Guidance About Materials Licenses'', NUREG 1757, Volume 1, ''Consolidated Decommissioning Guidance,'' various Inspection Procedures, and certain Inspection Manual Chapters to make changes to conform with this rulemaking effort. To support an accelerated development schedule for this proposed rule, the updates will be made in a future revision of the guidance, rather than concurrently with this rulemaking. However, for the new SGL program that is proposed in 10 CFR part 31 subpart C, the NRC has drafted interim guidance to aid licensees and the NRC in implementation of the new licensing option. The NRC has also drafted interim staff guidance to address the revised reciprocity requirements in § 150.20, using a Frequently Asked Questions format. The interim guidance will be added to the NRC's public website. You may submit comments on the draft interim guidance by the methods outlined in the **ADDRESSES** section of this document

XVIII. Executive Orders

The following are Executive orders that are related to this proposed rule:

A. Executive Order 12866: Regulatory Planning and Review (as Amended by Executive Order 14215, Ensuring Accountability for All Agencies)

The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is a

significant regulatory action. Accordingly, the NRC submitted this proposed rule to OIRA for review. The NRC is required to conduct an economic analysis in accordance with section 6(a)(3)(B) of E.O. 12866. More can be found in Section VII, of this document, ''Regulatory Analysis.''

B. Executive Order 14154: Unleashing American Energy

NRC has examined this proposed rule and has determined that it is consistent with the policies and directives outlined in E.O. 14154.

C. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is tentatively determined to be a deregulatory action as defined by E.O. 14192. Details on the estimated costs of this proposed rule can be found in Section VII, of this document, ''Regulatory Analysis.''

D. Executive Order 14267: Reducing Anti-Competitive Regulatory Barriers

E.O. 14267 requires the NRC to identify anti-competitive regulations for recission or modification. It also serves an important regulatory goal. The NRC identified § 30.4 because this regulation creates a barrier to market participation by creating artificial barriers to facility location related to consortiums and PET radionuclide production. In addition, NRC identified § 34.20(a)(1) because this regulation creates a barrier to market participation by limiting the universe of acceptable radiography designs. The NRC identified 10 CFR part 31 because this regulation creates a barrier to market participation by increasing the compliance requirements on all market participants. The proposed changes to 10 CFR part 31 support the objectives of E.O. 14267 by adding standard general licensing pathway and thereby expanding the scope of general licenses for byproduct material to include additional devices and more activities.

E. Executive Order 14270: Zero-Based Regulatory Budgeting To Unleash American Energy

E.O. 14270, ''Zero-Based Regulatory Budgeting to Unleash American Energy,'' requires the NRC to insert a conditional sunset date into all new or amended NRC regulations provided the regulations are (1) promulgated under the Atomic Energy Act of 1954, as amended (AEA), the Energy Reorganization Act of 1974, as amended (ERA), and the Nuclear Waste Policy Act of 1982, as amended (NWPA); (2) not statutorily required; and (3) not part of the NRC's permitting regime. The NRC determined that the regulatory changes proposed in this rule are required because they would be necessary for providing reasonable assurance of adequate protection of public health and safety and provide for the common defense and security, and would be part of the NRC's permitting regime authorized by the AEA. Therefore, the NRC views this rulemaking to be outside the scope of E.O. 14270 and did not insert conditional sunset dates for the regulatory changes in this proposed rule.

XIX. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No./web link/**Federal Register** citation
Interim Staff Guidance Reciprocity	ML25316A025.
Office Of Nuclear Material Safety and Safeguards Interim Staff Guidance NMSS–ISG–04 Guidance for the Implementation of 10CFRPart31 Subpart C Standard General Licenses.	ML25316A026.
Final rule, ''Requirements for Expanded Definition of Byproduct Material,'' dated October 1, 2007	72 FR 55864.
Final rule, ''Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,'' dated October 16, 2007.	72 FR 58473.
Final rule, ''Standards for Protection Against Radiation; Removal of Expired Material,'' dated December 22, 1993	58 FR 67657.
Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Materials—Regulatory Basis.	ML21235A480.
PRM–30–66 Petition for Rulemaking, Revision of 10 CFR 30 Appendix B, April 14, 2017	ML17173A063.
SECY–23–0062, Enclosure 1—Proposed Rule **Federal Register** Notice for Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials, July 24, 2023.	ML23010A171.
Final rule, ''Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License Exemptions,'' dated May 29, 2013.	78 FR 32310.
Final rule, ''Safety Requirements for Industrial Radiographic Equipment,'' dated January 10, 1990	55 FR 843.
Final rule, ''Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations,'' dated May 28, 1997.	62 FR 28948.
Notification of interpretation, ''Industrial Radiographic Operations and Training,'' dated June 1, 2021	86 FR 29173.
Final rule, ''Licenses and Radiation Safety Requirements for Well Logging,'' dated April 17, 2000	65 FR 20345.
Final rule, ''Consumer Products Containing Small Quantities of Radioactive Material; Modified Reporting and Recordkeeping Requirements,'' dated March 24, 1983..	48 FR 12331.
PRM–30–66, ''Request of the Organization of Agreement States for the NRC to Amend Appendix B, 'Quantities of Licensed Material Requiring Labeling,'" dated April 14, 2017.	ML17173A063.
PRM–34–6, ''Petition for Rulemaking on behalf of the Organization of Agreement States (AOS), Barbara Hamrick to amend 10 CFR part 34,'' dated November 3, 2005.	ML053190112.
NUREG–1556, ''Consolidated Guidance About Materials Licenses''	*https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.*
NUREG–1717, ''Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials,'' June 2001.	ML011980433 (Package).
NUREG–1757, ''Consolidated Decommissioning Guidance,'' Volume 1, Revision 2, September 2006	ML063000243.
Regulatory Analysis for the Proposed Rule—Modernizing NRC Regulations for Byproduct Material Use	ML26125A393.
Redline Strikeout Document—Proposed Rule—Modernizing NRC Regulations for Byproduct Material Use	ML25323A157 (Package).
Revision to policy statement, ''Agreement State Program Policy Statement; Correction,'' dated October 18, 2017	82 FR 48535.
Regulatory basis; request for comment, ''Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials,'' dated April 28, 2022.	87 FR 25157.
Executive Order 12866, ''Regulatory Planning and Review,'' October 4, 1993	58 FR 51735.
Executive Order 14154, ''Unleashing American Energy,'' January 29, 2025	90 FR 8353.

Document	ADAMS accession No./web link/**Federal Register** citation
Executive Order 14192, ''Unleashing Prosperity Through Deregulation,'' February 6, 2025	90 FR 9065.
Executive Order 14270, ''Zero-Based Regulatory Budgeting To Unleash American Energy,'' April 15, 2025	90 FR 15643.
Burden Tables Modernizing Regulations for Byproduct Material use	ML25323A164.
Supporting Statement Modernizing Regulations for Byproduct Material Use	ML25322A158.
Presidential Memorandum, ''Plain Language in Government Writing,'' dated June 10, 1998	63 FR 31885.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2025–1205. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2025–1205); (2) click the ''Subscribe'' link; and (3) enter an email address and click on the ''Subscribe'' link.

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear energy, Nuclear materials, Penalties, Radiation protection, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 31

Byproduct material, Criminal penalties, Labeling, Nuclear energy, Nuclear materials, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear energy, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 34

Criminal penalties, Manpower training programs, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures, X-rays.

10 CFR Part 39

Byproduct material, Criminal penalties, Labeling, Nuclear energy, Nuclear material, Occupational safety and health, Oil and gas exploration—well logging, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Source material, Special nuclear material.

10 CFR Part 40

Criminal penalties, Exports, Government contracts, Hazardous materials transportation, Hazardous waste, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Source material, Uranium, Whistleblowing.

10 CFR Part 70

Classified information, Criminal penalties, Emergency medical services, Hazardous materials transportation, Material control and accounting, Nuclear energy, Nuclear materials, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material, Whistleblowing.

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing to amend 10 CFR parts 30, 31, 32, 34, 39, 40, 70 and 150:

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

■ 1. The authority citation for part 30 continues to read as follows:

Authority: Atomic Energy Act secs. 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2111, 2112, 2201, 2231, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–58, 119 Stat. 549 (2005).

Section 30.7 also issued under Energy Reorganization Act sec. 211, Pub. L. 95–601, sec. 10, as amended by Pub. L. 102–486, sec. 2902 (42 U.S.C. 5851). Section 30.34(b) also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 30.61 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

■ 2. In § 30.4, remove the definition of ''*Physician*'' and revise the definitions of ''*Consortium*'' and ''*Principle activities*'' to read as follows:

§ 30.4 Definitions.

* * * * *

Consortium means an association of medical use licensees and a PET radionuclide production facility that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

* * * * *

Principal activities, as used in this part and part 31 of this chapter, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal, and activities incidental to decontamination or decommissioning are not principal activities.

* * * * *

■ 3. In § 30.6, revise paragraph (b)(1) to read as follows:

§ 30.6 Communications.

* * * * *

(b) * * *

(1) The delegated licensing program includes authority to issue, renew, amend, cancel, modify, suspend, or revoke licenses for nuclear materials issued, and validate standard general license registrations, pursuant to 10 CFR parts 30 through 36, 39, 40, and 70 to all persons for academic, medical, and industrial uses, with the following exceptions:

* * * * *

■ 4. In § 30.32, revise paragraph (j)(2) to read as follows:

§ 30.32 Application for specific licenses.

* * * * *

(j) * * *

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in § 32.72(a) of this chapter.

* * * * *

■ 5. In § 30.34, revise paragraph (h)(1) to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(h) * * *

(1) Each general licensee that is required to register by § 31.5(c)(13) or part 31 subpart C in accordance with § 31.13 of this chapter, and each specific licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against:

* * * * *

■ 6. In § 30.35, revise paragraph (g) introductory text to read as follows:

§ 30.35 Financial assurance and recordkeeping for decommissioning.

* * * * *

(g) Each person licensed under this part, part 31 subpart C of this chapter, or parts 32 through 36 and 39 of this chapter shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with § 30.34(b), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of—

* * * * *

■ 7. In § 30.41, revise paragraph (d)(1) to read as follows:

§ 30.41 Transfer of byproduct material.

* * * * *

(d) * * *

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license, validated standard general license, or registration certificate;

* * * * *

■ 8. Revise appendix B to 10 CFR part 30 to read as follows:

Appendix B—Quantities of Licensed Material Used To Assess Financial Assurance for Decommissioning

Material	Micro-curies
Aluminum-26	10
Americium-241	0.01
Antimony-125	100
Argon-39	1,000
Barium-133	100
Berkelium-249	0.1
Beryllium-10	1
Bismuth-207	10
Bismuth-210m	0.1
Cadmium-109	10
Cadmium-113m	0.1
Cadmium-113	100
Calcium-41	100
Calcium-45	100
Californium-248	0.01
Carbon-14	100
Cerium-139	100
Cerium-144	1
Cesium-134	10
Cesium-135	100
Cesium-137	10
Chlorine-36	10
Cobalt-57	100
Cobalt-60	1
Curium-242	0.01
Dysprosium-159	100
Europium-150	1
Europium-152	1
Europium-154	1
Europium-155	10
Gadolinium-151	10
Gadolinium-152	100
Gadolinium-153	10
Germanium-68	10
Gold-195	10
Hafnium-172	1
Hafnium-178m	0.1
Hafnium-182	0.1
Holmium-166m	1
Hydrogen-3	1,000
Indium-115	100
Iodine-129	1
Iridium-194m	10
Iron-55	100
Iron-60	1
Krypton-81	1,000
Krypton-85	1,000
Lanthanum-137	10
Lanthanum-138	100
Lead-202	10
Lead-205	100
Lutetium-173	10
Lutetium-174m	10
Lutetium-174	10
Lutetium-176	100
Lutetium-177m	10
Manganese-53	1,000
Manganese-54	100
Mercury-194	1
Molybdenum-93	10
Neptunium-235	100
Nickel-59	100
Nickel-63	100
Niobium-93m	10
Niobium-94	1
Osmium-194	1
Palladium-107	10
Platinum-193	1,000
Plutonium-239	0.01
Polonium-210	0.1
Potassium-40	100
Promethium-143	100
Promethium-144	10
Promethium-145	10
Promethium-146	1
Promethium-147	10
Radium-226	0.1
Radium-228	0.1
Rhenium-184m	10
Rhenium-186m	10
Rhenium-187	1,000
Rhodium-101	10
Rhodium-102m	10
Rhodium-102	10
Rubidium-87	100
Ruthenium-106	1
Samarium-145	100
Samarium-146	1
Samarium-147	100
Samarium-151	10
Selenium-79	100
Silicon-32	1
Silver-108m	1
Silver-100m	10
Sodium-22	10
Strontium-90	0.1
Tantalum-179	100
Technetium-97	1,000
Technetium-98	10
Technetium-99	100
Tellurium-121m	10
Tellurium-123	100
Terbium-157	10
Terbium-158	1
Thallium-204	100
Thorium-232	100
Thorium-natural [1]	100
Thulium-170	10
Thulium-171	10
Tin-119m	100
Tin-121m	100
Tin-123	10
Tin-126	10
Titanium-44	1
Tungsten-181	1,000
Uranium-233	0.01
Uranium-234	0.01
Uranium-235	0.01
Uranium-238	100
Uranium-natural [2]	100
Vanadium-49	1,000
Zinc-65	10
Zirconium-93	10
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition.	0.01
Any radionuclide other than alpha emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition.	0.1

[1] Based on alpha disintegration rate of Th-232, Th-230, and their daughter products.

[2] Based on alpha disintegration rate of U–238, U–234, and U–235.

* * * * *

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

■ 9. The authority citation for part 31 continues to read as follows:

Authority: Atomic Energy Act secs. 81, 161, 183, 223, 234 (42 U.S.C. 2111, 2201, 2233, 2273, 2282); Energy Reorganization Act secs. 201, 202 (42 U.S.C. 5841, 5842); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

■ 10. Add subpart A, before § 31.1 to read as follows:

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

Subpart A—General Information

§ 31.1 Purpose and scope.

* * * * *

■ 11. In § 31.4, revise paragraph (b) and add paragraph (c)(2) to read as follows:

§ 31.4 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 31.5, 31.8, 31.11, 31.12, 31.13, 31.14, 31.15, 31.16, 31.17, and 31.18.

(c) * * *

(2) In § 31.13, NRC Form 1003 is approved under control number 3150–XXXX.

* * * * *

■ 12. Add subpart B, before § 31.5, and revise paragraphs (c)(14) and (15) to read as follows:

Subpart B—General Licenses

§ 31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.[2]

* * * * *

c. * * *

(14) Shall report changes to the mailing address for the location of use (including change in name of general licensee) within 30 days of the effective date of the change by electronic submission such as Electronic Information Exchange, email to *GLTS.Resource@nrc.gov,* or CD–ROM; via mail to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 for mail where a signature is not required; or via mail to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, MD 20852–2738 for signature required correspondence. For a portable device, a report of address change is only required for a change in the device's primary place of storage. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC 's website at *https://www.nrc.gov/site-help/e-submittals.html;* by email to *MSHD.Resource@nrc.gov;* or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

(15) May not hold devices that are not in use for longer than 36 months. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (c)(2) of this section need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the 36 month time limit if the general licensee performs semi-annually physical inventories of these devices while they are in standby.

■ 13. In § 31.11, revise paragraphs (a)(3), (a)(4), (a)(6) and (a)(8) to read as follows:

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

(a) * * *

(1) * * *

(3) Carbon-14, in units not exceeding 100 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen-3 (tritium), in units not exceeding 1000 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) * * *

(6) Selenium-75, in units not exceeding 100 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(7) * * *

(8) Cobalt-57, in units not exceeding 100 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

* * * * *

■ 14. Add subpart C, consisting of §§ 31.13 through 31.18, to read as follows:

Subpart C—Standard General Licenses

Subpart C—Standard General Licenses

§ 31.13 Standard General License Requirements.

(a) Any person, as defined in § 30.4 of this chapter, engaging in standard general license activities described in § 31.14–31.18 of this part, shall:

(1) At least 30 calendar days prior to acquiring, receiving possessing, using, or transferring byproduct material, file a submittal containing an NRC Form 1003, with the Commission using a communication method defined in § 30.6(a) of this chapter;

(2) Receive from the Commission, a validated standard general license in the form of a copy of NRC Form 1003 with a registration number assigned; and

(3) Pay the appropriate fee as prescribed in § 170.31 of this chapter. No fee will be required to accompany an amendment of a standard general license, except as provided in § 170.31 of this chapter.

(b) A standard general licensee under this subpart shall:

(1) Limit the number of locations of use to no more than five locations of use, excluding temporary job sites as permitted by the standard general licenses in § 31.15 and § 31.17 of this part.

(2) File a submittal containing an NRC Form 1003, with the Commission using a communication method defined in § 30.6(a) of this chapter, at least 30 calendar days prior to the effective date

of any of the following changes to the most recently validated NRC Form 1003: the licensee's direct ownership, controlling ownership of the licensed activities, name of the licensee, location of use addresses, mailing address, Radiation Safety Officer, or materials.

(i) If licensed activities are transferred or assigned to a different ownership, each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated: Records of disposal of licensed material made under §§ 20.2002 (including burials authorized before January 28, 1981[1]), 20.2003, 20.2004, 20.2005; and Records required by § 20.2103(b)(4) of this chapter.

(3) Pay an annual fee as prescribed in § 171.16 of this chapter.

(c) A person licensed under this subpart shall restrict the possession of licensed material:

(1) To a total quantity below unity for the radionuclides listed in 10 CFR part 37 appendix A, calculated using the Category 2 activity thresholds specified in the table, according to 10 CFR part 37 appendix A;

(2) To quantities below the minimum limits for unsealed and/or sealed material as specified in § 30.35(d) of this chapter for which decommissioning financial assurance is required; and

(3) To quantities below the limits specified in § 30.72 of this chapter, in the form of unsealed material and foil or plated sources, above which, consideration of the need for an emergency plan for responding to a release of licensed material is required.

(d) A person licensed under this subpart shall not abandon byproduct material.

(e) A person licensed under this subpart shall not export the byproduct material except in accordance with part 110 of this chapter.

(f)(1) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the Commission by filing a submittal containing an NRC Form 1003 with the Commission using a communication method defined in § 30.6(a) of this chapter any of the following and indicate which approach under paragraph (f)(2) of this section the licensee intends to pursue:

(i) The licensee has decided to permanently cease principal activities, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Commission requirements, or

(ii) No principal activities under the license have been conducted for a period of 36 months, or

(iii) No principal activities have been conducted for a period of 36 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

(2) When notification is made pursuant to paragraph (f)(1) of this section, the licensee must—

(i) Within 45 days, submit a request to delay initiation of decommissioning activities consistent with paragraph (g) of this section, or

(ii) Immediately begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with NRC requirements, or

(iii) Within 12 months, submit a decommissioning plan, if required by paragraph (f)(3) of this section, and begin decommissioning upon approval of that plan.

(3)(i) A decommissioning plan must be submitted if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any cases described in § 30.36(g)(1)(i)–(iv).

(ii) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (f)(2) of this section if the Commission determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(iii) Procedures such as those listed in paragraph (f)(3)(i) of this section with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(iv) The proposed decommissioning plan for the site or separate building or outdoor area must include the information listed in § 30.36 (g)(4)(i)–(vi):

(v) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(4) Licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(5) When decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(6) As the final step in decommissioning, the licensee shall—

(i) Certify the disposition of all licensed material, including accumulated wastes, by filing a submittal containing an NRC Form 1003, with the Commission using a communication method defined in § 30.6(a) of this chapter; and

(ii) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E. The licensee shall, as appropriate—

(A) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters—removable and fixed—for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(B) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(g) The Commission may grant a request to extend the time periods established in paragraph (f). The schedule for decommissioning set forth in paragraph (f) of this section may not commence until the Commission has made a determination on the request. The request must include the following:

(1) Discussion of the business need for continued possession or authorization of licensed material or how the request is otherwise in the public interest.

(2) Discussion of the health and safety plan that will be in effect during the extension period.

(3) Discussion of the current decommissioning cost estimate and the potential for increased decommissioning costs if an extension of the time period is approved.

(4) A timeframe for which principal activities will resume, which shall not exceed 36 months from the date that principal activities ceased at the site, separate building, or outdoor area, as provided for in (f)(1)(ii) and (f)(1)(iii) of this section.

(5) A commitment that, should principal activities not resume within the timeframe specified in paragraph (g)(4), the licensee shall submit provide notification to the NRC consistent with paragraph (f) of this section.

(h) A licensee shall terminate a standard general license with the Commission by filing a submittal containing an NRC Form 1003, with the Commission using a communication method defined in § 30.6(a) of this chapter. The standard general license will be terminated by written notice to the licensee when the Commission determines that:

(i) Byproduct material has been properly disposed;

(ii) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(iii)(A) A radiation survey has been performed which demonstrates that the premises are suitable for unrestricted release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E; or

(B) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for unrestricted release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E.

(iv) Records required by § 30.51 (d) and (f) of this chapter have been received.

§ 31.14 Standard General License for Certain Fixed Gauging.

(a)(1) Provided that the provisions of paragraph (b) of this section have been met, a general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use, or transfer byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, or qualitative or quantitative chemical composition in accordance with the provisions of paragraph (c) of this section.

(2)(i) The provisions of paragraph (a)(1) of this section apply to byproduct material contained in devices which are registered in the Sealed Source and Device Registry with the Commission under § 32.210, as defined in § 32.2 of this chapter, or with an Agreement State, with the principle use codes D—gamma gauges or E—beta gauges.

(ii) The provisions of paragraph (a)(1) of this section apply to the use specifically licensed devices that are distributed in accordance with § 30.41 of this chapter.

(3) The provisions of paragraph (a)(1) of this section apply for use of these materials at fixed locations listed on the most recent NRC Form 1003 provided to the Commission in accordance with § 31.13 of this part.

(4) The provisions of paragraph (a)(1) of this section do not authorize the manufacture, initial transfer or distribution, or import of devices containing byproduct material.

(b)(1) The general licenses provided in this section are subject to all the provisions of the Act, now or hereafter in effect, and to all applicable rules, regulations, and orders of the Commission including the provisions of §§ 30.7, 30.8, 30.9, 30.10, 30.11, 30.31, 30.34, 30.35, 30.41, 30.50 through 30.64 of this chapter; §§ 31.1 through 31.4 of this part; §§ 31.21 through 31.23 of this part; and to the provisions of 10 CFR parts 19, 20, 21, and 71.

(2) Any person engaging in activities under the general licenses provided in this section need not comply with § 30.34(b) of this chapter.

(3) In addition, any person engaging in activities under the general licenses provided in this section shall comply with the requirements in § 31.13 of this part.

(c) A licensee shall —

(1)(i) Limit the use of sealed sources to those registered either with Commission under § 32.210 of this chapter or with an Agreement State.

(ii) Ensure sealed sources are incorporated in compatible devices, by manufacturer and model, and limited to use as specified in the Sealed Source and Device Registry for the devices manufacturer and model.

(iii) Ensure the activity of byproduct material in sealed sources is limited to the activity listed in the Sealed Source and Device Registry for the associated devices manufacturer and model.

(2)(i) Appoint and designate, in writing, a radiation safety officer responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(ii) Maintain a record of an individual's training and experience, and appointment as the Radiation Safety Officer for 5 years following their last day in the role.

(3)(i) Designate, in writing, individuals to work as authorized users, who have sufficient training and experience to use and supervise the use of licensed materials. Additionally, Licensee staff engaged in leak test sample collection, on-off mechanism testing, and routine maintenance shall be trained on the licensee's procedures and the manufacturer's written recommendations and instructions for the relevant activities.

(ii) Maintain the designation and record of the individuals' training and experience for 5 years after the individuals last works as an Authorized User for the licensee.

(4) Ensure licensed materials authorized by paragraph (a) of this section are used by, or under the supervision of, individuals who have been designated as authorized users by paragraph (c)(3) of this section.

(5)(i) Operate each device containing byproduct material within the manufacturer's specified temperature and environmental limits such that shielding and shutter mechanisms of the source holder are not comprised.

(ii) Ensure sealed sources containing licensed material are not opened and sources are not removed from source holders.

(iii) Ensure only the gauge manufacturer, distributor, or other person authorized by the Commission or an Agreement State will perform nonroutine maintenance such as installation, initial radiation survey, repair and maintenance of radiological safety components, relocation, replacement, alignment, removal from service, and disposal of sealed sources.

(6)(i) Prepare an evaluation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in § 20.1502 of this chapter; or

(ii) Develop, implement, and maintain a program for individual monitoring of external and internal occupational dose in accordance with § 20.1502 of this chapter.

(iii) maintain records of the evaluation described in (6)(i) for 3 years following the last use of licensed material by unmonitored individuals.

(iv) maintain records of individual monitoring results in accordance with § 20.2106 of this chapter.

(7)(i) Ensure any radiation detection instruments used to perform on-off

mechanism tests and surveys required by this part, 10 CFR part 20, and 10 CFR part 30 are appropriate for the isotopes and activities present and meet the requirements of § 20.1501 of this chapter.

(ii) Ensure the instruments used for required surveys are calibrated at least annually by a person licensed by the Commission or an Agreement State to perform instrument calibration services.

(iii) Maintain a record of the calibration for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(8)(i) Conduct physical inventories every 6 months to account for all sealed sources and/or devices received and possessed under the license.

(ii) Maintain records of inventories for 3 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

(9) Ensure sealed sources and detector cells are tested for leakage periodically.

(i)The licensee shall keep a record of leak test results in units of becquerels (microcuries) and retain the record for inspection by the Commission for 3 years after the leak test is performed. The final leak test record performed prior to the sealed source or detector cell being transferred or disposed of shall be retained until the license is terminated. Records must also show the dates of performance and the names of persons performing testing.

(ii) Ensure leak tests are performed by an organization licensed by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits and/or sample analysis services to other licensees and according to the kit supplier's instructions. The leak test sample must be taken from the nearest accessible point to the sealed source or detector cell where contamination might accumulate. The leak test sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 Bq [0.005 microcuries] of radioactive material on the test sample and is performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

(iii)(A) Ensure each sealed source, except sealed sources and detector cells designed to primarily emit alpha particles, are tested at intervals specified either in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under § 32.210 of this chapter or by an Agreement State. In the absence of a registration certificate, sealed sources or detector cell shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.

(B) Ensure sealed sources and detector cells designed to primarily emit alpha particles are tested for leakage and/or contamination at intervals not to exceed 3 months.

(C) Ensure that, in the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the Commission under § 32.210 of this chapter or by an Agreement State, prior to the transfer, a sealed source or detector cell received from another person not be put into use until tested and the test results received.

(iv)(A) Ensure that, if the test conducted pursuant to paragraphs (i) and (ii) of this section reveals the presence of 185 becquerels (0.005 microcuries) or more of removable contamination, a report shall be filed with the Commission in accordance with § 30.50(c)(2) of this chapter, and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

(B) Submit a report to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter, within 5 days of receiving the test results. The report must describe the equipment involved in the leak, the test results, any contamination which resulted from the leaking source, and the corrective actions taken up to the time the report is made.

(v) Exempt the following sealed sources and detector cells from the periodic leak test requirements set out in paragraphs (i) through (iv) of this section:

(A) Hydrogen-3 (tritium) sources;

(B) Sources containing licensed material with a half-life of 30 days or less;

(C) sources containing licensed material in gaseous form;

(D) Sources of beta- or gamma-emitting radioactive material with an activity of 3.7 MBq [100 microcuries] or less; and

(E) Sources of alpha- or neutron-emitting radioactive material with an activity of 0.37 MBq [10 microcuries] or less.

(F) Sealed sources if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

(10)(i) Test each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months. This requirement does not apply to gauges that are in storage with the shutter mechanism is in the locked position.

(ii) Maintain on-off mechanism test records for 3 years. The record must include the model and serial number of the device, the date of the test, the results of the test, and the name of the individual who performed the test.

(11) Develop, implement, and maintain procedures for routine maintenance of gauges according to each manufacturer's or distributor's written recommendations and instructions.

(12) Develop, implement, and maintain operating, emergency, and security procedures that meet the requirements of §§ 19.11(a)(3), 20.1101, 20.1801–1802, 20.2201–2203, 2207, 21.21, and 30.50 of this chapter.

§ 31.15 Standard General License for Portable Gauging.

(a)(1) Provided that the provisions of paragraph (b) of this section have been met, a general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use, or transfer, byproduct material contained in devices designed and manufactured for the purpose of measuring the physical properties of materials in accordance with the provisions of paragraph (c) of this section.

(2)(i)The provisions of paragraph (a)(1) of this section apply to byproduct material contained in devices which are registered in the Sealed Source and Device Registry with the Commission under § 32.210 of this chapter, as defined in § 32.2 of this chapter, or with an Agreement State, with the principle use codes G—Portable Moisture Density Gauges.

(ii) The provisions of paragraph (a)(1) of this section apply to the use of specifically licensed devices that are distributed in accordance with § 30.41 of this chapter.

(3)(i) The provisions of paragraph (a)(1) of this section authorize use, possession and storage of licensed materials at fixed locations listed on the most recent NRC Form 1003 provided to the Commission in accordance with § 31.13 of this part; and

(ii) Use, possession and storage of licensed materials at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee shall contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction.

(iii) Authorization for use of radioactive materials at job sites in Agreement States in areas not under exclusive Federal jurisdiction is not provided under this general license and shall be obtained from the appropriate State regulatory agency.

(4) The provisions of paragraph (a)(1) of this section do not authorize the manufacture, initial transfer or distribution, or import of devices containing byproduct material

(b)(1)The general licenses provided in this section are subject to all the provisions of the Act, now or hereafter in effect, and to all applicable rules, regulations, and orders of the Commission including the provisions of §§ 30.7,30.8, 30.9, 30.10, 30.11, 30.31, 30.34, 30.35, 30.41, 30.50 through 30.64 of this chapter; §§ 31.1 through 31.4 of this part; §§ 31.21 through 31.23 of this part; and to the provisions of 10 CFR parts 19, 20, 21, and 71.

(2) Any person engaging in activities under the general licenses provided in this section need not comply with § 30.34(b) of this chapter.

(3) In addition, any person engaging in activities under the general licenses provided in this section shall comply with the requirements in § 31.13 of this part.

(c) The licensee shall—

(1)(i) Limit the use of sealed sources to those registered either with Commission under § 32.210 of this chapter or with an Agreement State.

(ii) Ensure sealed sources are incorporated in compatible devices, by manufacturer and model, and limited to use as specified in the Sealed Source and Device Registry for the devices manufacturer and model.

(iii) Ensure the activity of byproduct material in sealed sources is limited to the activity listed in the Sealed Source and Device Registry for the associated devices manufacturer and model.

(2)(i) Appoint and designate, in writing, a radiation safety officer responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(ii) Maintain a record of an individual's training and experience, and appointment as the Radiation Safety Officer for 5 years following their last day in the role.

(3)(i) Designate, in writing, individuals to work as authorized users, who have completed a portable gauge safety course for users and hands-on training in the use of portable gauges.

(ii) Maintain the designation and record of the individual's training and experience for 5 years after the individual last works as an Authorized User for the licensee.

(4) Ensure licensed materials authorized by paragraph (a) of this section are used by, or under the supervision of, individuals who have been designated as authorized users by paragraph (c)(3) of this section.

(5)(i) Prepare an evaluation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in § 20.1502 of this chapter; or

(ii) Develop, implement, and maintain a program for individual monitoring of external and internal occupational dose in accordance with § 20.1502 of this chapter.

(iii) maintain records of the evaluation described in (5)(i) for 3 years following the last use of licensed material by unmonitored individuals.

(iv) maintain records of individual monitoring results in accordance with § 20.2106 of this chapter.

(6)(i) Possess and use, or have access to and use, a radiation detection instrument for surveys required by parts 20 and 71 of this chapter.

(ii) Ensure the instruments used for required surveys are calibrated at least annually by a person licensed by the Commission or an Agreement State to perform instrument calibration services.

(7)(i) Develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times.

(ii) Conduct Physical inventories every 6 months to account for all sealed sources and/or devices received and possessed under the license.

(iii) Maintain records of inventories for 3 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

(8) Ensure sealed sources are tested for leakage periodically.

(i) The licensee shall keep a record of leak test results in units of becquerels (microcuries) and retain the record for inspection by the Commission for 3 years after the leak test is performed. The final leak test record performed prior to the sealed source being transferred or disposed of shall be retained until the license is terminated. Records must also show the dates of performance and the names of persons performing testing.

(ii) Ensure leak tests are performed by an organization licensed by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits and/or sample analysis services to other licensees and according to the kit supplier's instructions. The leak test sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate. The leak test sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 Bq [0.005 microcuries] of radioactive material on the test sample and is performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

(iii)(A) Ensure each sealed source, except sealed sources designed to primarily emit alpha particles, are tested at intervals specified either in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under § 32.210 of this chapter or by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.

(B) Ensure sealed sources designed to primarily emit alpha particles are tested for leakage and/or contamination at intervals not to exceed 3 months.

(C) Ensure, that in the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate

of registration issued by the Commission under § 32.210 of this chapter or by an Agreement State, prior to the transfer, a sealed source received from another person not be put into use until tested and the test results received.

(iv)(A) Ensure, that if the test conducted pursuant to paragraphs (i) and (ii) of this section reveals the presence of 185 becquerels (0.005 microcuries) or more of removable contamination, a report shall be filed with the Commission in accordance with § 30.50(c)(2) of this chapter, and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

(B) Submit a report to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter, within 5 days of receiving the test results. The report must describe the equipment involved in the leak, the test results, any contamination which resulted from the leaking source, and the corrective actions taken up to the time the report is made.

(v) Exempt the following sealed sources from the periodic leak test requirements set out in paragraphs (i) through (iv) of this section:

(A) Hydrogen-3 (tritium) sources;

(B) Sources containing licensed material with a half-life of 30 days or less;

(C) sources containing licensed material in gaseous form;

(D) Sources of beta- or gamma-emitting radioactive material with an activity of 3.7 MBq [100 microcuries] or less; and

(E) Sources of alpha- or neutron-emitting radioactive material with an activity of 0.37 MBq [10 microcuries] or less.

(F) Sealed sources if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

(9) Develop, implement, and maintain procedures for routine maintenance of gauges according to each manufacturer's or distributor's written recommendations and instructions.

(10) Develop, implement, and maintain operating, emergency, and security procedures that meet the requirements of §§ 20.1101, 20.1801 through 1802, 20.2201 through 2203, 30.34, and 30.50 of this chapter.

§ 31.16 Standard General License for Certain Medical Uses.

(a)(1) Provided that the provisions of paragraph (b) of this section have been met, a general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to manufacture, produce, acquire, receive, possess, prepare, use, or transfer, byproduct material for certain medical uses in accordance with the provisions of paragraph (c) of this section.

(2) The provisions of paragraph (a)(1) of this section apply for use of:

(i) Unsealed gallium-67, indium-111, iodine-123, iodine-125, iodine-131), technetium-99m, thallium-201, and xenon-133 for uptake, dilution, excretion, imaging, and localization studies for which a written directive is not required for medical uses as described in §§ 35.100 and 35.200 of this chapter;

(ii) Molybdenum-99/technetium-99m generators to prepare radiopharmaceuticals for medical uses as described in §§ 35.100 and 35.200 of this chapter; and

(iii) Calibration, transmission, and reference sources for uses as described in § 35.65 of this chapter.

(3)(i) The provisions of paragraph (a)(1) of this section do not apply for use of unsealed byproduct material for mobile medical services as defined in § 35.2.

(ii) The provisions of paragraph (a)(2)(iii) do not apply for use of sources for medical use as defined in § 35.2 of this chapter including with the requirements § 35.500 of this chapter.

(4) The provisions of paragraph (a)(1) of this section apply for use of these materials at fixed locations listed on the most recent NRC Form 1003 provided to the Commission in accordance with § 31.13 of this part.

(b)(1)The general licenses provided in this section are subject to all the provisions of the Act, now or hereafter in effect, and to all applicable rules, regulations, and orders of the Commission including the provisions of §§ 30.7, 30.8, 30.9, 30.10, 30.11, 30.31, 30.34, 30.35, 30.41, 30.50 through 30.64 of this chapter; §§ 31.1 through 31.4 of this part; §§ 31.21 through 31.23 of this part; and to the provisions of 10 CFR parts 19, 20, 21, 35 with the exceptions provided in paragraph (b)(2) of this section, and 10 CFR part 71.

(2) Any person engaging in activities under the general licenses provided in this section need not comply with § 30.34(b) of this chapter and §§ 35.11, 35.12, 35.13, 35.14, 35.18, 35.24(a)-(b), and 35.24(d),of this chapter.

(3) In addition, any person engaging in activities under the general licenses provided in this section shall comply with the requirements in § 31.13 of this part.

(c) A licensee shall—

(1)(i) Designate, in writing, an individual to work as the Radiation Safety Officer, as defined in 10 CFR 35.2 who meets the training and experience requirements in § 35.50 of this chapter to be responsible for implementing the radiation protection program.

(ii) Ensure the individual working as Radiation Safety Officer meets the training, experience and criteria established in § 35.59 of this chapter.

(iii) Maintain the designation and record of the individual's training and experience for 5 years after the individual last works as a Radiation Safety Officer for the licensee.

(iv) For the time period described in § 35.24(c) of this chapter, a licensee may permit an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59 of this chapter, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in § 35.24(g) of this chapter, if the licensee takes the actions required in paragraphs (2)(i)-(iii) of this paragraph and the required actions in §§ 35.24(e), 35.24(g), and 35.24(h) of this chapter and notifies the Commission in accordance with § 31.13 of this chapter.

(2)(i) Designate, in writing, individuals to work as authorized users, as defined in § 35.2 of this chapter who meet the training and experience requirements in § 35.190 of this chapter for § 35.100 activities § 35.290 of this chapter for § 35.200 activities.

(ii) Ensure individuals working as authorized users meet the training, experience and criteria established in § 35.59 of this chapter.

(iii) Maintain the designation and record of the individual's training and experience for 5 years after the individual last works as an Authorized User for the licensee.

(3) Ensure licensed materials authorized by paragraph (a) of this section are used by, or under the supervision of, individuals who have been designated as authorized users by paragraph (c)(2) of this section.

(4)(i) Prepare an evaluation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in § 20.1502 of this chapter; or

(ii) Develop, implement, and maintain a program for individual monitoring of external and internal occupational dose

in accordance with § 20.1502 of this chapter.

(iii) maintain records of the evaluation described in (4)(i) for 3 years following the last use of licensed material by unmonitored individuals.

(iv) maintain records of individual monitoring results in accordance with § 20.2106 of this chapter.

(5)(i) Ensure any radiation detection instruments used to perform surveys required by this part, 10 CFR parts 20, 30, 35, and 71 are appropriate for the isotopes and activities present and meet the requirements of § 20.1501 of this chapter.

(ii) Ensure the instruments used for required surveys are calibrated at least annually by a person licensed by the Commission or an Agreement State to perform instrument calibration services.

(iii) Maintain a record of the calibrations for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(6)(i) Develop, implement, and maintain written procedures for sealed-source leak testing that meet the requirements of § 35.67 of this chapter; or

(ii) Ensure leak test sample collection and analysis is performed by an organization authorized by the Commission or an Agreement State to provide leak testing services to other licensees; or

(iii) Use a leak test sample collection kit supplied by an organization licensed by the Commission or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit;

(iv) Maintain records of leak testing in accordance with § 35.2067(a) of this chapter.

(7) Develop, implement, and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of §§ 20.1101 and 20.1201 of this chapter.

(8) Develop, implement, and maintain written procedures for safe response to spills of licensed material in accordance with § 20.1101 of this chapter.

(9) Develop, implement, and maintain written procedures for area surveys in accordance with § 20.1101 of this chapter that meet the requirements of §§ 20.1501 and 35.70 of this chapter.

(10) Develop, implement, and maintain written procedures for licensed material accountability and control to ensure that: license possession limits are not exceeded; licensed material in storage is secured from unauthorized access or removal; licensed material not in storage is maintained under constant surveillance and control; records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained.

(11) Develop, implement, and maintain written procedures for a program for training required under § 19.12 of this chapter for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training.

(12) Develop, implement, and maintain written waste disposal procedures for licensed material in accordance with § 20.1101 of this chapter, that also meet the requirements of the applicable section of 10 CFR part 20, subpart K, and of § 35.92 of this chapter.

§ 31.17 Standard General License for Certain Analytical Equipment Including Electron Capture Detectors, X-Ray Fluorescence Devices, and Ion Generators.

(a)(1) Provided that the provisions of paragraph (b) of this section have been met, a general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use, or transfer, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, or qualitatively or quantitatively assessing chemical composition, or for producing an ionized atmosphere in accordance with the provisions of paragraph (c) of this section.

(2)(i) The provisions of paragraph (a)(1) of this section apply to byproduct material contained in devices which are registered in the Sealed Source and Device Registry with the Commission under § 32.210 of this chapter, as defined in § 32.2 of this chapter, or with an Agreement State, with the principle use codes N—Ion Generators, Chromatography, or U—X-Ray Fluorescence.

(ii) The provisions of paragraph (a)(1) of this section apply to the use of specifically licensed devices that are distributed in accordance with § 30.41 of this chapter.

(3)(i) The provisions of paragraph (a)(1) of this section authorize use, possession and storage of licensed materials at fixed locations listed on the most recent NRC Form 1003 provided to the Commission in accordance with § 31.13 of this part; and

(ii) Temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee shall contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction.

(iii) Authorization for use of radioactive materials at job sites in Agreement States in areas not under exclusive Federal jurisdiction is not provided under this general license, and shall be obtained from the appropriate State regulatory agency.

(4) The provisions of paragraph (a)(1) of this section do not authorize the manufacture, initial transfer or distribution, or import of devices containing byproduct material.

(b)(1)The general licenses provided in this section are subject to all the provisions of the Act, now or hereafter in effect, and to all applicable rules, regulations, and orders of the Commission including the provisions of §§ 30.7, 30.8, 30.9, 30.10, 30.11, 30.31, 30.34, 30.35, 30.41, 30.50 through 30.64 of this chapter; §§ 31.1 through 31.4 of this part; §§ 31.21 through 31.23 of this part; and to the provisions of 10 CFR parts 19, 20, 21, and 71.

(2) Any person engaging in activities under the general licenses provided in this section need not comply with § 30.34(b) of this chapter.

(3) In addition, any person engaging in activities under the general licenses provided in this section shall comply with the requirements in § 31.13 of this chapter.

(c) A licensee shall—

(1)(i) Limit the use of sealed sources to those registered either with Commission under § 32.210 of this chapter or with an Agreement State.

(ii) Ensure sealed sources are incorporated in compatible devices, by manufacturer and model, and limited to use as specified in the Sealed Source and Device Registry for the devices manufacturer and model.

(iii) Ensure the activity of byproduct material in sealed sources is limited to the activity listed in the Sealed Source and Device Registry for the associated devices manufacturer and model.

(2)(i) Appoint and designate, in writing, a radiation safety officer responsible for having knowledge of the appropriate regulations and

requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(ii) Maintain a record of an individual's training, and appointment as the Radiation Safety Officer for 5 years following their last day in the role.

(3)(i) Ensure detector cells containing a titanium tritide foil or scandium tritide foil are only used in conjunction with a properly operating temperature control mechanism that prevents the foil temperature from exceeding that specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission pursuant to § 32.210 of this chapter or equivalent regulations from an Agreement State.

(ii) Ensure when in use, detector cells containing a titanium tritide foil or scandium tritide foil are vented to the outside.

(iii) Ensure sealed sources, source rods, foil sources, or detector cells containing licensed material are not opened or sources removed from source holders or detached from source rods, or foil sources removed from detector cells.

(iv) Except for maintaining labeling as required by 10 CFR part 20 or 10 CFR part 71, the licensee shall not make any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective certificate of registration issued either by the U.S. Nuclear Regulatory Commission pursuant to § 32.210 of this chapter or by an Agreement State.

(v) Ensure maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells or of sealed sources is performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

(4)(i) Conduct Physical inventories every 6 months to account for all sealed sources and/or devices received and possessed under the license.

(ii) Maintain records of inventories for 3 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

(5) Ensure sealed sources and plated foil sources are tested for leakage periodically.

(i) The licensee shall keep a record of leak test results in units of becquerels (microcuries) and retain the record for inspection by the Commission for 3 years after the leak test is performed. The final leak test record performed prior to the sealed source or foil plated source being transferred or disposed of shall be retained until the license is terminated. Records must also show the dates of performance and the names of persons performing testing.

(ii) Ensure leak tests are performed by an organization licensed by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits and/or sample analysis services to other licensees and according to the kit supplier's instructions. The leak test sample must be taken from the nearest accessible point to the sealed source or plated foil sources where contamination might accumulate. The leak test sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 Bq [0.005 microcuries] of radioactive material on the test sample and is performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

(iii)(A) Ensure each sealed source, except sealed sources and plated foil sources designed to primarily emit alpha particles, are tested at intervals specified either in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under § 32.210 of this chapter or by an Agreement State. In the absence of a registration certificate, sealed sources or foil plated source shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.

(B) Ensure sealed sources and plated foil sources designed to primarily emit alpha particles are tested for leakage and/or contamination at intervals not to exceed 3 months.

(C) Ensure, that in the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the Commission under § 32.210 of this chapter or by an Agreement State, prior to the transfer, a sealed source or plated foil sources received from another person not be put into use until tested and the test results received.

(iv)(A) Ensure, that if the test conducted pursuant to paragraphs (i) and (ii) of this section reveals the presence of 185 becquerels (0.005 microcuries) or more of removable contamination, a report shall be filed with the Commission in accordance with § 30.50(c)(2) of this chapter, and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

(B) Submit a report to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter, within 5 days of receiving the test results. The report must describe the equipment involved in the leak, the test results, any contamination which resulted from the leaking source, and the corrective actions taken up to the time the report is made.

(v) Exempt the following sealed sources and plated foil sources from the periodic leak test requirements set out in paragraphs (i) through (iv) of this section:

(A) Hydrogen-3 (tritium) sources;

(B) Sources containing licensed material with a half-life of 30 days or less;

(C) sources containing licensed material in gaseous form;

(D) Sources of beta- or gamma-emitting radioactive material with an activity of 3.7 MBq [100 microcuries] or less; and

(E) Sources of alpha- or neutron-emitting radioactive material with an activity of 0.37 MBq [10 microcuries] or less.

(F) Sealed sources if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

(6)(i) Test each analytical instrument, as applicable, for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months. This requirement does not apply to analytical instruments that are in storage with the shutter lock mechanism is in the locked position.

(ii) Maintain on-off mechanism test records for 3 years. The record must include the model and serial number of the device, the date of the test, the results of the test, and the name of the individual who performed the test.

§ 31.18 Standard General License for Certain In Vitro Testing.

(a)(1) Provided that the provisions of paragraph (b) of this section have been met, a general license is hereby issued

to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use, or transfer, byproduct material for certain in vitro clinical or laboratory test in accordance with the provisions of paragraph (c) of this section.

(2) The provisions of paragraph (a)(1) of this section apply for use of materials listed in § 31.11(a)(1)–(8) of this part.

(3) The provisions of paragraph (a)(1) of this section do not apply for use of licensed materials in or on humans.

(4) The provisions of paragraph (a)(1) of this section do not authorize the use of licensed material in field applications where radioactivity is released.

(5) The provisions of paragraph (a)(1) of this section apply for use of these materials at fixed locations listed on the most recent NRC Form 1003 provided to the Commission in accordance with § 31.13 of this part.

(b)(1) The general licenses provided in this section are subject to all the provisions of the Act, now or hereafter in effect, and to all applicable rules, regulations, and orders of the Commission including the provisions of §§ 30.7, 30.8, 30.9, 30.10, 30.11, 30.31, 30.34, 30.35, 30.41, 30.50 through 30.64 of this chapter; §§ 31.1 through 31.4 of this part; §§ 31.21 through 31.23 of this part; and to the provisions of 10 CFR parts 19, 20, 21, and 71.

(2) Any person engaging in activities under the general licenses provided in this section need not comply with § 30.34(b) of this chapter or § 31.11 of this part.

(3) In addition, any person engaging in activities under the general licenses provided in this section shall comply with the requirements in § 31.13 of this part.

(c) A licensee shall—

(1)(i) Appoint and designate, in writing, a radiation safety officer responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(ii) Maintain a record of an individual's training and experience, and appointment as the Radiation Safety Officer for 5 years following their last day in the role.

(2)(i) Designate, in writing, individuals to work as authorized users, who have sufficient training and experience to use and supervise the use of licensed materials.

(ii) Maintain the designation and record of the individuals' training and experience for 5 years after the individuals last works as an Authorized User for the licensee.

(3) Ensure licensed materials authorized by paragraph (a) of this section are used by, or under the supervision of, individuals who have been designated as authorized users by paragraph (c)(3) of this section.

(4)(i) Prepare an evaluation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in § 20.1502 of this chapter; or

(ii) Develop, implement, and maintain a program for individual monitoring of external and internal occupational dose in accordance with § 20.1502 of this chapter.

(iii) maintain records of the evaluation described in (5)(i) for 3 years following the last use of licensed material by unmonitored individuals.

(iv) maintain records of individual monitoring results in accordance with § 20.2106 of this chapter.

(5)(i) Ensure any radiation detection instruments used to perform surveys required by this part, 10 CFR parts 20, 30, and 71 are appropriate for the isotopes and activities present and meet the requirements of § 20.1501 of this chapter.

(ii) Ensure the instruments used for required surveys are calibrated at least annually by a person licensed by the Commission or an Agreement State to perform instrument calibration services.

(iii) Maintain a record of the calibrations for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(6)(i) Dispose of radioactive waste in accordance with 10 CFR part 20.

(ii) Where appropriate, hold radioactive material with a physical half-life of less than or equal to 275 days for decay-in-storage before disposal in ordinary trash provided:

(A) Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(B) A record of each such disposal permitted under this license requirement shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

(iii) Waste from *in vitro* kits, except mock I–125, that are generally licensed under § 31.11 of this part are exempt from waste disposal regulations in 10 CFR part 20, as set forth in § 31.11(f). Radioactive labels shall be defaced or removed. There is no need to keep any record of release or make any measurement.

(7) Develop, implement, and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of §§ 20.1101 and 20.1201 of this chapter.

(8) Develop, implement, and maintain written procedures for safe response to spills of licensed material in accordance with § 20.1101 of this chapter.

(9) Develop, implement, and maintain written procedures for area surveys in accordance with § 20.1101 of this chapter that meet the requirements of § 20.1501 of this chapter.

(10) Develop, implement, and maintain written procedures for licensed material accountability and control to ensure that: license possession limits are not exceeded; licensed material in storage is secured from unauthorized access or removal; licensed material not in storage is maintained under constant surveillance and control; records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained.

(11) Develop, implement, and maintain written procedures for a program for training required under § 19.12 of this chapter for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training.

(12) Develop, implement, and maintain written waste disposal procedures for licensed material in accordance with § 20.1101 of this chapter, that also meet the requirements of the applicable section of 10 CFR part 20, subpart K.

§ 31.19–31.20 [Reserved]

■ 15. Add subpart D, before § 31.21 to read as follows:

Subpart D—Records

§ 31.21 Maintenance of records.

* * * * *

■ 16. Add subpart E, before § 31.22 to read as follows:

Subpart E—Enforcement

§ 31.22 Violations.

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PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

■ 17. The authority citation for part 32 continues to read as follows:

Authority: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

■ 18. Revise and republish § 32.12 to read as follows:

§ 32.12 Same: Records of material transfer.

(a) Each person licensed under § 32.11 shall maintain records of transfer of byproduct material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.14 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.

(b) The record must identify the:

(1) Type and quantity of each product or material into which byproduct material has been introduced by calendar year, if applicable;

(2) Name and address of the person who owned or possessed the product or material, into which byproduct material has been introduced, at the time of introduction;

(3) The type and quantity of radionuclide introduced into each product or material; and

(4) The initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee.

(c) The licensee shall maintain the record of a transfer in accordance with § 30.51.

■ 19. Revise and republish § 32.16 to read as follows:

§ 32.16 Certain items containing byproduct material: Records of transfer.

(a) Each person licensed under § 32.14 shall maintain records of all transfers of byproduct identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.15 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.

(b) The record must include the following information:

(1) A description or identification of the type of each product and the model number(s), if applicable;

(2) For each radionuclide in each type of product and each model number, if applicable, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred by calendar year and model number, if applicable;

(c) The licensee shall maintain the record of a transfer in accordance with § 30.51.

■ 20. Revise and republish § 32.20 to read as follows:

§ 32.20 Same: Records of material transfer.

(a) Each person licensed under § 32.18 shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.

(b) The record must include the following information:

(1) For each radionuclide in each physical form, the record shall indicate the total quantity of each radionuclide and the physical form, transferred under the specific license.

(c) The licensee shall maintain the record of a transfer in accordance with § 30.51 of this chapter.

■ 21. Revise and republish § 32.25 to read as follows:

§ 32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and records of transfer.

Each person licensed under § 32.22 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the product and the byproduct material in the product can be identified; and

(c) Each person licensed under § 32.22 shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.19 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.

(1) The record must include the following information:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide; and

(iii) The number of units of each type of product transferred by calendar year and model number, if applicable.

(b) The licensee shall maintain the record of a transfer in accordance with § 30.51.

■ 22. Revise and republish § 32.29 to read as follows:

§ 32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and records of transfer.

Each person licensed under § 32.26 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each detector and its point-of-sale package so that:

(1) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(i) The following statement: ''CONTAINS RADIOACTIVE MATERIAL'';

(ii) The name of the radionuclide and quantity of activity; and

(iii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State.

(2) The labeling or marking specified in paragraph (b)(1) of this section is located where its will be readily visible when the detector is removed from its mounting.

(3) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(i) The name of the radionuclide and quantity of activity;

(ii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement: THIS DETECTOR

CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

(4) Each detector and point-of-sale package is provided with such other information as may be required by the Commission; and

(c) Each person licensed under § 32.26 shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.20 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.

(1) The record must include the following information:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide; and

(iii) The number of units of each type of product transferred by calendar year and model number, if applicable.

(d) The licensee shall maintain the record of a transfer in accordance with § 30.51.

■ 23. Revise and republish § 32.32 to read as follows:

§ 32.32 Conditions of licenses issued under § 32.30: Quality control, labeling, and records of transfer.

Each person licensed under § 32.30 shall:

(a) Carry out adequate control procedures in the manufacture of the device to ensure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each device and its point-of-sale package so that:

(1) Each item has a durable, legible, readily visible label or marking on the external surface of the device containing:

(i) The following statement: ''CONTAINS RADIOACTIVE MATERIAL'';

(ii) The name of the radionuclide(s) and quantity(ies) of activity;

(iii) An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and

(iv) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information).

(2) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(i) The name of the radionuclide and quantity of activity;

(ii) An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement: ''THIS DEVICE CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NUCLEAR REGULATORY COMMISSION SAFETY CRITERIA IN 10 CFR 32.31. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.''

(3) Each device and point-of-sale package contains such other information as may be required by the Commission; and

(c) Each person licensed under § 32.30 shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.22 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.

(1) The record must include the following information:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide; and

(iii) The number of units of each type of product transferred by calendar year and model number, if applicable.

(d) The licensee shall maintain the record of a transfer in accordance with § 30.51.

■ 24. Revise and republish § 32.72 to read as follows:

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs or preparation or transfer for commercial distribution microsources containing byproduct material for medical use under part 35.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs, or to prepare or transfer for commercial distribution microsources containing byproduct material for use by persons authorized pursuant to part 35 of this chapter or § 31.16 will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(2) The applicant submits evidence that it is legally authorized, under applicable Federal or State law, to manufacture, compound, prepare, or distribute radioactive drugs or medical devices, including those regulated under 21 CFR part 207, 21 CFR part 212, or 21 CFR part 820, as applicable;

(3) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug or microsources; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs or microsources by medical use licensees; and

(4) The applicant commits to the following labeling requirements:

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of radioactive drugs or microsources to be transferred for commercial distribution. The label must include the radiation symbol and the words ''CAUTION, RADIOACTIVE MATERIAL'' or ''DANGER, RADIOACTIVE MATERIAL''; the name of the radioactive drug, microsource, or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs or microsources with a half-life greater than 100 days, the time may be omitted.

(ii) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug or microsources to be transferred for commercial distribution. The label must include the radiation symbol and the words ''CAUTION, RADIOACTIVE MATERIAL'' or ''DANGER, RADIOACTIVE MATERIAL'' and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label, and

(iii) A label is affixed in accordance with the Sealed Source and Device Registry, as applicable.

(b) A licensee that meets the requirements of paragraph (a)(2) and is licensed as a pharmacy by a State Board of Pharmacy or that is operating as a nuclear pharmacy within a Federal medical institution:

(1) May prepare radioactive drugs or microsources for medical use, as defined in § 35.2 of this chapter, provided that the radioactive drug or microsources are prepared by either an authorized nuclear pharmacist, as specified in paragraphs (b)(2) and (b)(4) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.

(2) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in § 35.2 of this chapter;

(ii) This individual meets the requirements specified in § 35.55(b) and 35.59 of this chapter, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (b)(4) of this section.

(3) The actions authorized in paragraphs (b)(1) and (b)(2) of this section are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist (as defined in § 35.2 of this chapter) as an authorized nuclear pharmacist if:

(i) The individual was a nuclear pharmacist preparing only radioactive drugs or microsources containing accelerator-produced radioactive material; and

(ii) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(5) Shall provide to the Commission:

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter; or

(ii) The Commission or Agreement State license, or

(iii) Commission master materials licensee permit, or

(iv) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(vi) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs and microsources. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs or microsources prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

(d) A licensee shall satisfy the labeling requirements in paragraph (a)(4) of this section.

(e) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or microsources.

■ 25. In § 32.74, revise section heading, paragraphs (a) introductory text, (a)(2) introductory text, (a)(2)(ii), (a)(2)(viii), (a)(3) and (b)(1) to read as follows:

§ 32.74 Manufacture and distribution of sources, microsources, or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources, microsources, or devices containing byproduct material to persons licensed under part 35 of this chapter or § 31.16 of this chapter for use as a calibration, transmission, or reference source or for the medical uses listed in part 35 of this chapter will be approved if:

(1) * * *

(2) The applicant submits sufficient information regarding each type of source, or device pertinent to an evaluation of its radiation safety, including:

(i) * * *

(ii) Details of design and construction of the source, or device;

* * * * *

(viii) Instructions for handling and storing the source, or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source, or device: *Provided,* That instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(3) The label affixed to the source or device, or to the permanent storage container for the source, or device, contains information on the radionuclide, quantity and date of assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source, or device) to persons licensed to use byproduct material identified in §§ 35.65, 35.400, 35.500, 35.600, 35.700, and 35.1000 of this chapter as appropriate, and to persons who hold an equivalent license issued by an Agreement State.

* * * * *

(b) * * *

(1) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

PART 34—LICENSES FOR INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

■ 26. The authority citation for part 34 continues to read as follows:

Authority: Atomic Energy Act secs. 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704, (44 U.S.C. 3504 note). Atomic Energy Act of 2005 sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111)

Section 34.45 also issued under Energy Reorganization Act sec. 206 (42 U.S.C. 5846).

■ 27. In § 34.3, add in alphabetical order the definition for *Sealed Source and Device Registry* to read as follows:

* * * * *

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both the NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

* * * * *

■ 28. In § 34.13, revise paragraph (b) and remove paragraphs (b)(1) and (b)(2). The revision reads as follows:

§ 34.13 Specific license for industrial radiography.

* * * * *

(b) The applicant submits an adequate program for training radiographers and radiographers' assistants that meets the requirements of § 34.43. A license applicant need not describe its initial training and examination program for radiographers in the subjects outlined in § 34.43(g).

* * * * *

§ 34.20 [Amended]

■ 29. Amend § 34.20 by:
■ a. Revising paragraphs (a)(1) and (a)(2);
■ b. Removing paragraph (c)(8) and redesigning paragraph (c)(9) as paragraph (c)(8); and
■ d. Removing paragraphs (d) and (e).

The revisions read as follows:

§ 34.20 Performance requirements for industrial radiography equipment.

* * * * *

(a) * * *

(1) Each radiographic exposure device, source assembly or sealed source must have been evaluated by the NRC or an Agreement State and registered in the Sealed Source and Device Registry, and all associated equipment must meet the manufactures' specifications and instructions.

(2) Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the Commission may find this an acceptable alternative to actual testing of the component pursuant to the requirements referenced in paragraph (a)(1) of this section.

* * * * *

§ 34.23 [Amended]

■ 30. In § 34.23, in paragraph (a) remove the phrase ''§ 34.51'' and add in its place the phrase ''§ 34.41''.

§ 34.27 [Amended]

■ 31. Amend § 34.27 by:
■ a. In the first sentence of (c)(1), add the phrase ''or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry'', after the phrase ''6 months'';
■ b. In paragraph (e), removing the phrase ''Licensees will have until June 27, 1998, to comply with the DU leak-testing requirements of this paragraph''.

§ 34.33 [Amended]

■ 32. In § 34.33, in paragraph (b) remove the phrase ''§ 34.51'' and add in its place the phrase ''§ 34.41''.

■ 33. Revise and republish § 34.41 to read as follows:

§ 34.41 Conducting industrial radiographic operations.

(a) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of § 34.43(c). Radiography may not be performed if only one qualified individual is present.

(1) During each radiographic operation either the radiographer or the other qualified individual present shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in 10 CFR part 20 of this chapter.

(2) The second individual present must be in sufficiently close proximity to the radiographic operation and sufficiently aware of the ongoing activities to be able to provide immediate assistance when necessary and to prevent unauthorized entry.

(b) All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the Commission.

(c) A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Commission or by an Agreement State.

■ 34. Amend § 34.43 by:
■ a. Revising paragraph (a) and removing paragraphs (a)(1) and (2); and
■ b. Removing paragraphs (h) and (i).

The revision reads as follows:

§ 34.43 Training.

(a) The licensee may not permit any individual to act as a radiographer until the individual has received training in the subjects in paragraph (g) of this section, in addition to a minimum of 2 months of on-the-job training, and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in appendix A of this part. (An independent organization that would like to be recognized as a certifying entity shall submit its request to the Director, Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter.)

* * * * *

§ 34.51 [Reserved]

■ 35. Remove and reserve § 34.51.
■ 36. In § 34.89, revise paragraph (b) to read as follows:

§ 34.89 Location of documents and records.

* * * * *

(b) Each licensee shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;

(1) The license authorizing the use of licensed material;

(2) Utilization records for each radiographic exposure device dispatched from that location as required by § 34.71.

(3) Records of alarm system and entrance control checks required by § 34.75, if applicable;

(4) Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeters readings as required by § 34.83;

(5) Current operating and emergency procedures required by § 34.81;

(6) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by § 34.65;

(7) Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by § 34.83;

(8) Latest survey records required by § 34.85;

(9) The shipping papers for the transportation of radioactive materials required by § 71.5 of this chapter; and

(10) When operating under reciprocity pursuant to § 150.20 of this chapter, a copy of the Agreement State license authorizing the use of licensed materials.

* * * * *

§ 34.101 [Amended]

■ 37. In § 34.101, remove and reserve paragraph (c).

PART 39—LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

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

Authority: Atomic Energy Act secs. 53, 57, 62, 63, 65, 69, 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2112, 2201, 2231, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note).

§ 39.33 [Amended]

■ 39. In § 39.33, in paragraph (c)(1), remove the phrase ''6 months'' and add in its place the phrase ''12 months''.
■ 40. In § 39.35, revise paragraph (c)(1) to read as follows:

§ 39.35 Leak testing of sealed sources.

* * * * *

(c) Each sealed source (except an energy compensation source (ECS)) must be tested at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry. In the absence of a certificate from a transferor that a test has been made within the 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry before the transfer, the sealed source may not be used until tested.

* * * * *

■ 41. In § 39.77, remove paragraph (c)(1) and redesignate paragraphs (c)(2) and (c)(3) as paragraphs (c)(1) and (c)(2).

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

■ 42. The authority citation for part 40 continues to read as follows:

Authority: Atomic Energy Act secs. 11(e)(2), 62, 63, 64, 65, 81, 161, 181, 182, 183, 186, 193, 223, 234, 274, 275 (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2231, 2232, 2233, 2236, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Public Law 109–59, 119 Stat. 594 (2005).

Section 40.7 also issued under Energy Reorganization Act sec. 211, Public Law 95–601, sec. 10, as amended by Public Law 102–486, sec. 2902 (42 U.S.C. 5851). Section 40.31(g) also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152). Section 40.46 also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 40.71 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

■ 43. Revise and republish § 40.53 to read as follows:

§ 40.53 Conditions for licenses issued for initial transfer of certain items containing source material: Quality control, labeling, and records.

(a) Each person licensed under § 40.52 shall ensure that the quantities or concentrations of source material do not exceed any applicable limit in § 40.13(c).

(b) Each person licensed under § 40.52 shall ensure that each product is labeled as provided in the specific exemption under § 40.13(c) and as required by their license. Those distributing products to be used under § 40.13(c)(1)(i) and (iii) or equivalent regulations of an Agreement State shall provide radiation safety precautions and instructions relating to handling, use, and storage of these products as specified in the license.

(c)(1) Each person licensed under § 40.52 shall maintain record of transfer.

(2) The record must clearly identify the specific licensee preparing the record and include the license number of the specific licensee and indicate that the products are transferred for use under § 40.13(c), giving the specific paragraph designation, or equivalent regulations of an Agreement State.

(3) The record must include the following information on products transferred to other persons for use under § 40.13(c) or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s), if applicable;

(ii) For each type of source material in each type of product and each model number, if applicable, the total quantity of the source material; and

(iii) The number of units of each type of product transferred by calendar year and model number, if applicable.

(4) The licensee shall maintain the record of a transfer and all information concerning transfers in accordance with § 40.61.

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

■ 44. The authority citation for part 70 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57(d), 108, 122, 161, 182, 183, 184, 186, 187, 193, 223, 234, 274, 1701 (42 U.S.C. 2071, 2073, 2077(d), 2138, 2152, 2201, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

§ 70.25 [Amended]

■ 45. Amend § 70.25 by:

■ a. In paragraph (a)(2), remove the phrase ''unsealed special nuclear material'' and add in its place the phrase ''unsealed special nuclear material of half-life greater than 120 days and''; and

■ b. In paragraph (b) introductory text, remove the phrase ''unsealed special nuclear material'' and add in its place the phrase ''unsealed special nuclear material of half-life greater than 120 days''.

PART 150—EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

■ 46. The authority citation for part 150 continues to read as follows:

Authority: Atomic Energy Act sec. 161, 181, 223, 234 (42 U.S.C. 2201, 2021, 2231, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Public Law 109–58, 119 Stat. 594 (2005).

Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under Atomic Energy Act secs. 11e(2), 81, 83, 84 (42 U.S.C. 2014e(2), 2111, 2113, 2114). Section 150.14 also issued under Atomic Energy Act sec. 53 (42 U.S.C. 2073). Section 150.15 also issued under Nuclear Waste Policy Act secs. 135 (42 U.S.C. 10155). Section 150.17a also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152). Section 150.30 also issued under Atomic Energy Act sec. 234 (42 U.S.C. 2282).

§ 150.14 [Reserved]

■ 47. Remove and reserve § 150.14.

■ 48. Revise and republish § 150.20 to read as follows:

§ 150.20 Recognition of Agreement State licenses.

(a)

(1) Provided that the provisions of paragraph (b) of this section have been met, any person who holds a specific license or a standard general license from an Agreement State, where the licensee maintains an office for directing the licensed activity and retaining radiation safety records, is granted a general license to conduct the same activity in—

(i) Non-Agreement States;

(ii) Areas of Exclusive Federal jurisdiction within Agreement States; and

(iii) Offshore waters.

(2) The provisions of paragraph (a)(1) of this section do not apply if the specific Agreement State license or Agreement State standard general license limits the authorized activity to a specific installation or location.

(b) Notwithstanding any provision to the contrary in any specific license issued by an Agreement State or standard general license granted by an Agreement State to a person engaging in activities in a non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters under the general licenses provided in this section, the general licenses provided in this section are subject to all the provisions of the Act, now or hereafter in effect, and to all applicable rules, regulations, and orders of the Commission including the provisions of §§ 30.7(a) through (f), 30.9, 30.10, 30.34, 30.41, and 30.51 through 30.63 of this chapter; §§ 40.7(a) through (f), 40.9, 40.10, 40.41, 40.51, 40.61 through 40.63, 40.71, and 40.81 of this chapter; §§ 70.7(a) through (f), 70.9, 70.10, 70.32, 70.42, 70.52, 70.55, 70.56, 70.60 through 70.62 of this chapter;

§§ 74.11, 74.15, and 74.19 of this chapter; and to the provisions of 10 CFR parts 19, 20 and 71 and subparts C through H of part 34, §§ 39.15 and 39.31 through 39.77 of this chapter. In addition, any person engaging in activities in non-Agreement States, in areas of exclusive Federal jurisdiction within Agreement States, or in offshore waters under the general licenses provided in this section:

(1) Shall, no later than the day of engaging in each activity for the first time in a calendar year, file a submittal containing an NRC Form 241, ''Report of Proposed Activities in Non-Agreement States,'' a copy of its Agreement State specific license or a copy of its validated Agreement State standard general license, and the appropriate fee as prescribed in § 170.31 of this chapter with the Regional Administrator of the U.S. Nuclear Regulatory Commission Regional Office listed on the NRC Form 241 and in appendix D to part 20 of this chapter for the Region in which the Agreement State that issued the license is located.

(2) Shall file an amended NRC Form 241 for changes in work locations except for activities performed offshore, radioactive material, or work activities different from the information contained on the initial NRC Form 241.

(3) Shall not, in any non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters, transfer or dispose of radioactive material possessed or used under the general licenses provided in this section, except by transfer to a person who is specifically licensed by the Commission to receive this material.

(4) Shall not, under the general license concerning activities in non-Agreement States or in areas of exclusive Federal jurisdiction within Agreement States, possess or use radioactive materials, or engage in the activities authorized in paragraph (a) of this section, for more than 180 days in any calendar year, except that the general license in paragraph (a) of this section concerning activities in offshore waters authorizes that person to possess or use radioactive materials, or engage in the activities authorized, for an unlimited period of time.

(5) Shall comply with all terms and conditions of the specific license issued by an Agreement State, or as applicable, comply with the terms and conditions of the standard general license granted by an Agreement State, except such terms or conditions as are contrary to the requirements of this section.

Dated: May 14, 2026.

For the Nuclear Regulatory Commission.

Carrie Safford,

Secretary of the Commission.

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