THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 70

[NRC-2017-0031]

RIN 3150-AK52

Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for decommissioning financial assurance for sealed and unsealed radioactive materials. The rulemaking would revise NRC's decommissioning funding requirements for radioactive material based on the relative risk to public health and safety from different radioisotopes, including naturally occurring and accelerator-produced radioactive material. The potentially affected licensees are those authorized to possess radioactive material licenses. The NRC plans to hold a public meeting to promote full understanding of the proposed rule and facilitate public comments.

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

DATES: Submit comments by **[INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the **Federal rulemaking website**:

- **Federal rulemaking website:** Go to https://www.regulations.gov and search for Docket ID NRC-2017-0031. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; email: Dawn.Forder@nrc.gov. For technical questions contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Email comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.

- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

FOR FURTHER INFORMATION CONTACT: Gregory Trussell, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-6244, email: Gregory.Trussell@nrc.gov, and Adam Schwartzman, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-8172, and email: Adam.Schwartzman@nrc.gov, Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001

SUPPLEMENTARY INFORMATION:

TABLE OF CONTENTS:

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2017-0031 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-2017-0031.

- **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 "Begin Web-based ADAMS 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

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.
in the "Availability of Documents" section.

- **NRC's PDR**: You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. 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 8:00 a.m. and 4:00 p.m. eastern time, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the **Federal rulemaking website** (https://www.regulations.gov). Please include Docket ID NRC-2017-0031 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. Background

This section discusses the background, requests for revisions to the NRC regulations, and existing regulatory framework relative to the Decommissioning Financial Assurance (DFA) requirements for sealed and unsealed radioactive material.

A. NRC Decommissioning Financial Assurance Regulations Final Rule of 1988

On June 27, 1988, the NRC published in the *Federal Register* its first comprehensive set of regulations addressing the decommissioning of nuclear facilities, "Final Rule: General Requirements for Decommissioning Nuclear Facilities" (53 FR 24018). These regulations were the result of a thorough review over multiple years of issues associated with the decommissioning of nuclear facilities as described in numerous SECY papers and Staff Requirements Memorandums (SRMs), contractor reports, *Federal Register* notices, a generic environmental impact statement, public meetings, and comment analysis.[1] The purpose of the rule was to assure that, at the

[1] These documents include (1) January 10, 1978, SECY-78-13, "Recommendations on Course of Action for Establishing Nuclear Facility Decommissioning Requirements" (ADAMS Accession No. ML22063A141); (2) January 31, 1978, SECY-78-13A, "Supplemental Information to SECY-78-

time operations were terminated (including premature closure of nuclear facilities), adequate funds would be available to complete decommissioning in a safe and timely manner. The regulations addressed decommissioning planning needs, timing, funding methods, and environmental review requirements. Regarding DFA for sealed and unsealed radioactive material, the new 10 CFR 30.35 required licensees that possessed and used byproduct material with a half-life greater than 120 days to use the quantities in appendix C to 10 CFR part 20[2] to determine whether a Decommissioning Funding Plan (DFP) was needed. The regulation in 10 CFR 70.25 required licensees that possessed and used unsealed special nuclear material to refer to the quantities in appendix C to 10 CFR part 20 to determine whether a DFP was needed.

B. Origin and Basis of Appendix B to 10 CFR Part 30

13 'Recommendations on Course of Action for Establishing Nuclear Facility Decommissioning Requirements,'" (ADAMS Accession No. ML21252A614); (3) February 17, 1978, SRM-78-13, "Recommendations on Course of Action for Establishing Nuclear Facility Decommissioning Requirements," (ADAMS Accession No. ML22063A473); (4) March 13, 1978, "Advance Notice of Rulemaking for Decommissioning Criteria for Nuclear Facilities" (43 FR 10370); (5) June 22, 1979, "Response to and Partial Denial of Petition for Rulemaking Filed by the Public Interest Research Group, et al. (Docket No. PRM-50-22)," (44 FR 36523) which requested the Commission initiate rulemaking to promulgate regulations for nuclear power plant decommissioning; (6) May 5, 1980, "Proposed Rule: 'Decommissioning of Nuclear Facilities Regulation (10 CFR Parts 30, 40, 50, and 70)'" (45 FR 37011); (7) February 10,1981, "Decommissioning Criteria for Nuclear Facilities: Notice of Availability of Draft Generic Environment Impact Statement" (10 CFR Parts 30, 40, 50, and 70) (46 FR 11666); and (8) February 11, 1985, "Proposed Rule: "Decommissioning Criteria for Nuclear Facilities" (10 CFR Parts 30, 40, 50, 51, 70, and 72) (50 FR 5600).

[2] The NRC redesigned appendix C to 10 CFR part 20 as appendix B to 10 CFR part 30 as part of the December 22, 1993, amendment of the NRC's regulation, which is discussed in Section II of this document.

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

On December 22, 1993, the NRC published a final rule, "Standards for Protection Against Radiation; Removal of Expired Material." The rule made several minor conforming amendments to the NRC's standards for protection against radiation that were published on May 21, 1991 (56 FR 23360). It removed the text of the superseded standards and conformed references in the new 10 CFR part 20. Regarding DFA, the NRC redesignated appendix C to 10 CFR part 20 as appendix B to 10 CFR part 30. In turn, it revised 10 CFR 30.35 and 10 CFR 70.25 to eliminate references to "appendix C to 10 CFR part 20" and to insert references to "appendix B to 10 CFR part 30."

As a result, the appendix B to 10 CFR part 30 values continued to be based upon International Commission on Radiological Protection (ICRP) Publication 2. The NRC decided not to conform the appendix B to 10 CFR part 30 values to ICRP Publications 26 and 30 during the 1991 revision of 10 CFR part 20. The NRC had determined that its experience with the values in appendix C to 10 CFR part 20 over 30 years had shown that the values were generally adequate to determine the level of funding assurance required for decommissioning and, therefore, retained them.

C. The Existing Regulatory Framework

Either the NRC or an Agreement State regulates the Nation's use of radioactive materials. The following sections describe the regulatory processes for determining the need for a DFP, the basis for establishing the decommissioning funding level, and the role of the Agreement States in the process.

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

a. NRC Regulatory Program

The NRC's regulations in 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning," and the table in appendix B to 10 CFR part 30 are used together to determine the amount of DFA required for unsealed and sealed byproduct material. The regulations in 10 CFR 70.25, "Financial assurance and recordkeeping for decommissioning," and appendix B to 10 CFR part 30 are used together to determine the amount of DFA required for unsealed special nuclear material. As noted in 10 CFR 30.35(a)(1) and 10 CFR 70.25(a)(2), DFPs must be submitted when radionuclide concentrations exceed 1×10^{5} times the applicable quantities listed in the table in appendix B to 10 CFR 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 the table in appendix B to 10 CFR part 30 must also submit DFPs. The NRC gives additional details about these criteria in 10 CFR 30.35(d) and 10 CFR 70.25(d).

The table in 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-emitting and gamma- and beta-emitting radionuclides.

Some radioactive materials licensed under 10 CFR part 70 have a half-life less than or equal to 120 days. Appendix C to 10 CFR part 20 contains 12 radionuclides for plutonium that are licensed under 10 CFR part 70. Seven of these radionuclides have half-lives greater than 120 days, four have half-lives less than 11 hours, and the last

radionuclide, Pu-237, has a half-life of 45.2 days. As a part of the rulemaking, the NRC staff plans to include the seven plutonium radionuclides with half-lives greater than 120 days into the revised appendix B to 10 CFR part 30.

b. Agreement State Regulatory Program

Section 274 of the Atomic Energy Act of 1954 authorizes the NRC to enter into agreements with individual States, known as Agreement States, providing them the authority and responsibility for administering a regulatory program for the safe use of radioactive materials within their borders. For the duration of such agreements, the Agreement States have the authority to regulate the materials covered by the agreement for the protection of public health and safety and the environment from radiation hazards. The Agreement States are required to adopt regulations in accordance with the compatibility category designation assigned to each NRC regulation, as discussed in NRC Management Directive 5.9, "Adequacy and Compatibility of Program Elements for Agreement State Programs," dated April 26, 2018. Appendix B to 10 CFR part 30 is designated as Compatibility Category B, which means that the Agreement States will be required to adopt requirements that are essentially identical to those in the NRC's regulations, including the requirements for DFA for sealed and unsealed radioactive material. Other provisions, 10 CFR 30.35(a), (b), (e), and (g), relating to decommissioning funding are classified as Category Health & Safety (H&S). Category H&S are not required for purposes of compatibility. However, the State must adopt program elements in this category, that embody the basic H&S aspects of the NRC's

program elements. These sections are not planned to be revised as a part of this rulemaking.

D. Requests for Revisions to the NRC's Regulations

a. NRC Advisory Committee on the Medical Uses of Isotopes

Many radionuclides used in the diagnosis and treatment of diseases are not listed in appendix B to 10 CFR art 30. Two unlisted radionuclides, germanium (Ge)-68/gallium (Ga)-68, are of particular concern to those in the medical field. Radiopharmaceuticals labeled with Ga-68 have been proven to be effective in the early diagnosis and treatment of neuroendocrine tumors, including cancers of the prostate, liver, and pancreas. These types of cancers are difficult to diagnose and can spread through the body quickly. As a result, Ge-68-/Ga-68 generators[3] are vitally important in the early detection and treatment of these types of cancers. In addition to their enhanced diagnostic capabilities, Ga-68- labeled radiopharmaceuticals provide a lower effective dose to patients when compared to other radiopharmaceuticals. They also are less expensive and more accessible when compared to other diagnostic tools and therapies used in cancer treatment.

Because of the importance of Ge-68/Ga-68 generators in the diagnosis and treatment of prostate, liver, and pancreatic cancers, the Advisory Committee on the

[3] A Ge-68/Ga-68 radiopharmaceutical generator is a device used to extract the positron-emitting isotope Ga-68 from a source of decaying Ge-68. The parent isotope Ge-68 has a half-life of 271 days, which serves as the basis for DFA because it has a half-life greater than the 120-day criterion, while the daughter isotope, Ga-68, has a half-life of only 68 minutes. Because of its short half-life, in-hospital generator production of Ga-68 is the optimal production method.

Medical Uses of Isotopes (ACMUI) issued the "Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) Final Report," and addendum, dated August 12, 2015. In the report, the 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. The ACMUI also noted that patients treated with Ga-68 radiopharmaceuticals would receive nearly a fivefold reduction in effective dose when compared to other radiopharmaceuticals. Thus, the ACMUI recommended that the NRC address the DFP concerns relative to Ge-68/Ga-68 generators.

The NRC agreed with the ACMUI report that the DFP requirement could impede or limit patient access to the radiopharmaceuticals developed from Ge-68/Ga-68 generators and that a DFP is not necessary to ensure the safe decommissioning of facilities that use the generators. By memoranda dated July 29, 2016, (ADAMS Accession No. ML16082A415) and July 13, 2017 (ADAMS Accession No. ML17075A487), the NRC established a temporary process for granting exemptions to the DFP requirements related to the possession and use of Ge-68/Ga-68 radiopharmaceutical generators when certain conditions are met.

The NRC is using this temporary process to provide relief from certain requirements until a rulemaking could be completed that would provide a generic regulatory solution.

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

b. Organization of Agreement States Petition—Petition for Rulemaking (PRM)

In a petition for rulemaking, PRM 30-66, the Organization of Agreement States (OAS), requested that the NRC provide specific possession values for Naturally-Occurring and Accelerator-Produced Radioactive Materials (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 asserted the following:

- Without possession values for the unlisted radionuclides, regulators are forced to evaluate new products against the default criteria and apply overly burdensome financial assurance obligations or evaluate case-by-case exemptions.
- Patient health and safety are being compromised due to delays in licensing important diagnostic and therapeutic products that use radionuclides not listed in the table in appendix B to 10 CFR part 30.
- These licensing obstacles could discourage development of new products, diminishing the possibility of new innovative and beneficial options in both medical and industrial applications.
- 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 it to add appropriate radionuclides and their corresponding activities.

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

On August 23, 2017, the NRC published a *Federal Register* notice of docketing (82 FR 39971) and requested comments on issues raised in the petition. The comment period ended on December 6, 2017, and the agency received 20 comment letters (ADAMS Package Accession No. ML18038A879). Fifteen commenters explicitly supported rulemaking, and one commenter requested a generic exception that only rulemaking can provide. No commenters opposed rulemaking, but one letter, while supporting a rulemaking for medical licensees, indicated that rulemaking could result in exempting industrial uses from Atomic Energy Act of 1954 regulation under the guise of a medical purpose. Five commenters identified 10 radionuclides whose uses have been adversely affected by not being listed in appendix B to 10 CFR part 30.

c. SECY-19-0125 and Associated SRM-SECY-19-0125

The NRC sought Commission approval to initiate rulemaking in response to the OAS petition. The rulemaking would involve a revision to appendix B to 10 CFR part 30 and could involve a revision to 10 CFR 30.35 and 10 CFR 70.25. As discussed in SECY19-0125, this proposed rulemaking would do the following:

- Replace the listings and values in appendix B to 10 CFR part 30 with those of appendix C to 10 CFR part 20 for isotopes with a half-life greater than 120 days.
- Amend the title to the table in appendix B to 10 CFR part 30 to reflect its current use for DFA as opposed to labeling.

- Remove all radionuclides with a half-life of 120 days or less from the table in appendix B to 10 CFR part 30 since these radionuclides are not considered when assessing DFA requirements and developing site-specific DFPs.

In SRM-SECY-19-0125, "Staff Requirements—SECY 19 0125—Petition for Rulemaking and Rulemaking Plan on Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Material (PRM-30-66; NRC 2017 0159)," dated October 13, 2020, the Commission approved the initiation of rulemaking in response to PRM-30-66 to provide specific possession values for radionuclides that are not currently listed in appendix B to 10 CFR part 30. The Commission also approved the publication of the NRC's proposed *Federal Register* notice announcing the determination on this petition. The NRC published a *Federal Register* notice on November 27, 2020 (85 FR 75959), announcing that the agency would consider the issues raised in PRM-30-66 through the NRC's rulemaking process.

d. Regulatory Basis

On April 2, 2022, the NRC published in the *Federal Register* a notice requesting public comment on the regulatory basis. The regulatory basis document summarizes the current regulatory framework, describes the regulatory issues, evaluates alternatives, and presents a recommendation for revising appendix B to 10 CFR part 30. The regulatory basis proposes five alternatives: (1) keep the status quo, (2) update the list of radionuclides and the values in the table in appendix B to 10 CFR part 30, (3)

partially update appendix B to 10 CFR part 30 (add unlisted naturally occurring radionuclides and other radionuclides not currently listed to the existing table in appendix B to 10 CFR part 30), (4) develop a new process for assessing decommissioning funding costs, and (5) update appendix B to 10 CFR part 30 and develop a new process for assessing decommissioning funding costs (combines Alternative 2 and Alternative 4 in two rulemakings). The NRC chose Alternative 2, as this alternative addresses the issues as described in the petition as well as the direction of the Commission in the SRM.

The regulatory basis also includes cost estimates for the NRC, Agreement States, and Industry for each alternative. The NRC asked for public comment on the recommendation with particular interest in comments and supporting rationale from the public on the NRC's initial assumptions regarding the qualitative and quantitative costs and benefits of the rulemaking, as well as on alternatives to the current recommended approach.

e. NRC Observations on Stakeholder Feedback on the Regulatory Basis

The NRC reviewed the stakeholder feedback received on the regulatory basis to inform the development of this proposed rule and the draft regulatory analysis. The NRC received stakeholder feedback in several technical areas.

Table 1 provides references to the eight public comment submissions received on the regulatory basis. The NRC parsed each submission, depending on its length and

complexity, into one or more comments. This document presents the NRC's summaries and responses to these comments.

Table 1- ADAMS References for Public Comment Submission on the Regulatory Basis

Comment Submission ID	Commenter	ADAMS Accession Number
1	Richard Sheriff, Shertech Pharmacy	ML22178A206
2	Joseph Klinger, Low-Level Waste Forum, Inc	ML22178A205
3	Stanley Hampton, Eli Lilly and Company	ML22178A204
4	Anonymous	ML22180A030
5	Munir Ghesami, Society of Nuclear Medicine and Molecular Imaging	ML22180A031
6	Michael Guastella, Council on Radionuclides and Radiopharmaceuticals, Inc	ML22180A032
7	John Cardarelli, Health Physics Society	ML222180A033
8	Brady Jens	ML22180A034

The NRC has reviewed the comments and organized them by category and provided responses below. This document presents the NRC's summaries of and responses to these comments.

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

Comments and Responses

Support for the Proposed Rule

Comment summary: The Health Physics Society supports the NRC's recommendation as they believe the proposed revisions will address the petitioner's request while also updating the requirements to a more current scientific basis. Specifically, the proposed revisions will 1) update the values to a more up-to-date and risk-informed table that is based on the International Commission on Radiological Protection (ICRP) Publication 26/30 as compared to those from ICRP Publication 2 as used in the current table; 2) add NARM and Ga 68 to appendix B to 10 CFR part 30 and other unlisted radionuclides included in the NRC's regulatory authority under the Energy Policy Act of 2005; 3) remove decommissioning-related barriers to licensing Ga 68 imaging and other emerging medical and industrial technologies that use or plan to use unlisted and NARM radionuclides; 4) clarify that only radioactive materials with half-lives greater than 120 days are subject to DFAs; and 5) eliminate confusion over the application of appendix B to 10 CFR part 30 that has the same title as appendix C to 10 CFR part 20.

Comment summary: Eli Lilly and Company supports the NRC's preferred option that would update the list of radionuclides and values in appendix B to 10 CFR part 30. The table needs to be updated to reflect the increasing use of newer nuclides.

Comment summary: The Council on Radionuclides and Radiopharmaceuticals supports the NRC's proposed rulemaking to use appendix C to 10 CFR part 20 as the basis to update appendix B to 10 CFR part 30.

NRC Response: The NRC agrees with these comments, that support the rulemaking and the need to update the table in appendix B to 10 CFR part 30 to a more up-to-date and risk-informed table and clarifies that only radioactive materials with half-lives greater than 120 days are subject to DFA. The NRC agrees that an increasing use of newer nuclides are absent from the existing table which creates an unnecessary burden on some licensees. The NRC's proposed changes, based on the table in appendix C to 10 CFR part 20 incorporates these newer nuclides. The new proposed appendix B to 10 CFR part 30 will address concerns related to decommissioning financial assurance barriers for Ga 68 and Ge 68 generators and other emerging medical and industrial technologies. Finally, to avoid confusion over the application of appendix B to 10 CFR part 30 the NRC is proposing to change the title of appendix B to 10 CFR part 30 to reflect its current use for DFA.

Supports the Proposed Rule and additional rulemaking to update the NRC's process for assessing DFA

Comment: The Low-Level Radioactive Waste Forum, commented that the NRC should pursue alternative five as presented in the regulatory basis document. Alternative five addresses the immediate concerns raised by the petitioner (Alternative Two) and suggests a second rulemaking to address concerns with the existing regulations regarding DFA requirements in 10 CFR 30.35.

Comment: The Society of Nuclear Medicine and Molecular Imaging commented that the NRC should consider alternative five. It stated that this approach would develop a more up-to-date and risk-informed table of values for use in assessing decommissioning funding costs, which would address the concerns outlined in the petition and the direction provided by the Commission. Secondly, the NRC would pursue an additional rulemaking for a more modern, risk-informed approach for developing and maintaining an up-to-date DFP**.** The Society of Nuclear Medicine and Molecular Imaging stated that alternative 5 (combination of alternatives two and four) combines the benefits of accomplishing an expedited rulemaking while also incorporating forward-looking, extensive rulemaking.

NRC Response: The NRC partially agrees with these comments, regarding their support of updating the table in appendix B to 10 CFR part 30 to a more up-to-date and

risk-informed table which clarifies that only radioactive materials with half-lives greater than 120 days are subject to DFA. The NRC acknowledges the comments supporting alternative four in addition to alternative two. However, the NRC notes there is no plan in place to implement alternative four currently. Implementing alternative four would require Commission approval of another rulemaking. This does not preclude the NRC from pursuing alternative four in the future. The NRC agrees that several issues could be addressed by evaluating 10 CFR 30.35, however that is outside the scope of this rulemaking. Accordingly, the NRC cannot address these specific suggestions with this proposed rulemaking.

Cost to Licensees

Comment: The Council on Radionuclides and Radiopharmaceuticals commented that the current NRC regulatory framework for DFA has put an undue hardship on a potential license applicant. Due to the hardship, the licensee decided not to acquire the necessary financial assurances for the Ge 68/Ga 68 generator. Accordingly, the potential applicant was unable to use licensed material as intended.

Comment: Richard Sheriff, president, and owner of Shertech Pharmacy commented that the cost of maintaining a letter of credit, surety bond, or a trust agreement creates an undue burden for a small business entity.

Comment: Brady Jens, an owner of a small nuclear pharmacy in a rural area, commented that his company has attempted to receive financial assurance and the process is very cumbersome and expensive. The cost is such that it delays the ability to provide patient care in rural areas.

Comment: An anonymous nuclear pharmacist from a facility accelerator-produced radionuclides and Ge/Ga generators commented that decommissioning cost hurts the ability of a small business to remain viable. They asked for consideration for alternative measures when a small business returned the generators while also maintaining the safety of employees and the community.

NRC Response: The NRC disagrees in part with these comments. The NRC wants to clarify that although the change to the table in appendix B to 10 CFR part 30 will affect the applicability of 10 CFR 30.35 certification requirement, NRC applicants and licensees always have the option to submit a DFP in support of the financial assurance amount. While in some cases the financial assurance required for pursuant a DFP may be higher, it also may result in a lower amount for certain materials or devices like Ge 68/Ga 68 generators. This may address some of the concerns raised by small businesses.

Exemptions from DFPs and DFAs for Ge 68/Ga 68 generators

Comment: Richard Sheriff, president and owner of Shertech Pharmacy commented that the NRC should exempt licensees from the requirements from 10 CFR 30.35 for DFA for Ga 68 generators. The commenter provided details as to the cost of obtaining and maintaining decommissioning financial assurance.

Comment: Brady Jens, who owns a small nuclear pharmacy, commented that the NRC should exempt licensees from the requirements from 10 CFR 30.35 for DFA for Ga 68 generators.

Comment: Society of Nuclear Medicine and Molecular Imaging commented that the NRC should exempt generators used for medical use or in research from DFPs.

Comment: The Health Physics Society commented that the NRC should remove decommissioning-related barriers to licensing Ga 68 imaging and other emerging medical and industrial technologies that use or plan to use unlisted and NARM radionuclides.

NRC Response: The NRC disagrees in part with these comments regarding exemptions for DFPs. The NRC currently has granted a limited number of licensee-requested exemptions for medical licensees that use Ge-68/Ga-68 generators under certain conditions. These exemptions were approved in advance of pending rulemaking to generically resolve the issue. By providing a regulatory solution through rulemaking, the NRC would create a more stable framework for use by regulators, applicants, and

licensees. If the NRC does not complete this rulemaking, then the Ge-68/Ga-68 exemption requests would be reviewed on a case-by-case basis, where a licensee would need to demonstrate its unique circumstances that warrant an exemption. In addition, since many of these unlisted radionuclides are used in the medical field, if the NRC does not pursue this rulemaking, many users of these unlisted isotopes are likely to submit numerous additional requests for exemptions to the DFA requirements.

The proposed changes to Appendix B to 10 CFR part 30 addresses this issue by adding Ge 68 and Ga 68 to the table with a specific value. These values match up to the values in the July 29, 2016, memoranda. Once the rule becomes effective the NRC will need to address the status of the memoranda discussed above. However, the NRC notes that providing specific exemptions in our regulations for Ga generators would require a separate rulemaking which would change 10 CFR 30.32(h) or 30.35.

Threshold Levels in Proposed New Appendix B are Too High

Comment: Joseph Klinger, Chairman for the Low-Level Radioactive Waste Forum's Disused Sources Working Group commented that the NRC has established fixed dollar amounts of financial assurance for both sealed and unsealed radioactive material that has not been updated in nearly two decades. In addition, the threshold for requiring financial assurance is set too high resulting in risk significant sealed sources not requiring financial assurance. A new appendix B to 10 CFR part 30 will result in only a

limited number of the International Atomic Energy Agency Category I radioactive sealed sources requiring financial assurance.

NRC Response: The NRC agrees with this comment. The fixed dollar amounts of financial assurance for both sealed and unsealed radioactive material listed in 10 CFR 30.35 Financial assurance and recordkeeping for decommissioning, was last updated in 2003 (68 FR 57335, October 3, 2003). The fixed dollar amounts for decommissioning financial assurance listed in 10 CFR 30.35 may not reflect current labor, packaging, transportation, or radioactive material disposal costs. However, a revision of the fixed dollar amounts of financial assurance for sealed and unsealed radioactive material is outside the scope of this rulemaking.

The NRC also agrees that the financial assurance threshold for the disposal of several types of radioactive sealed sources may be too high. The NRC conducted a scoping study to determine whether additional financial planning requirements for end-of-life management for some radioactive byproduct material, particularly Radioactive Sealed Sources, were needed. Based on the scoping study, which is documented in SECY-16-0046, “Radioactive Byproduct Material Financial Scoping Study,” the NRC recommended that the financial assurance requirements in 10 CFR 30.35 be expanded to include all Category 1 and 2 byproduct material radioactive sealed sources tracked in the National Source Tracking System. The current financial assurance threshold for colbalt-60 and cesium-137 sealed sources is one million and ten million curies,

respectfully. The Commission approved the staff's recommendation to initiate a rulemaking to expand the NRC's financial assurance requirements in 10 CFR 30.35 to require financial assurance for disposition of Category 1 and 2 byproduct material Radioactive Sealed Sources tracked in the National Source Tracking System and this issue will be addressed in another rulemaking. As part of other rulemaking, the staff will consider whether financial assurance requirements should also be extended to Category 3 sources.

III. Discussion

I. What Action Is the NRC Taking?

The NRC would revise the current table in appendix B, “Quantities of Licensed Material Requiring Labeling,” to 10 CFR part 30 using the radionuclides and quantities from appendix C, “Quantities of Licensed Material Requiring Labeling,” to 10 CFR part 20, “Standards for Protection against Radiation,” including additional radionuclides not currently named in appendix B to 10 CFR part 30. These include radionuclides associated with industrial technologies and current and emerging medical uses. 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. Finally, the default values would be set to equal lowest values of the listed radionuclides:

0.001 microcuries (μCi) for alpha emitting radionuclides like uranium-235, and 0.01 μCi for the most restricted non alpha emitting radionuclides (e.g., lead-210). The NRC would also change the title to the table in appendix B to 10 CFR part 30 to reflect its current use for DFA as opposed to labeling. As a result of these changes, licensees, the NRC staff, and the Agreement States would have an up-to-date table with more risk-informed values for use when assessing DFA.

II. Why Is the NRC Taking This Action Now?

a) Commission Direction- SRM-SECY-19-0125

The NRC is proposing a revision to the table in appendix B, "Quantities of Licensed Material Requiring Labeling," to Title 10 of the *Code of Federal Regulations* part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." The proposed rulemaking would base the NRC's decommissioning funding requirements for radioactive material on the relative risk to public health and safety from different radioisotopes, including NARM. The NRC is taking this action in response to a PRM submitted by the OAS on April 14, 2017. In its petition, the OAS requested that the NRC provide specific possession values for NARM radionuclides not currently listed in appendix B to 10 CFR part 30, so that licensees using these radionuclides would not have to apply the default values to calculate decommissioning funding requirements or submit an exemption request. Licensees use appendix B to 10 CFR part 30 in conjunction with 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning," and 10 CFR 70.25, "Financial assurance and recordkeeping for

decommissioning," to determine the amount of DFA that is needed or whether a DFP is required. If the appendix does not include a particular radionuclide, licensees must use default values that may result in licensees needing more DFA than is warranted based on the risk to public health and safety.

The current values in appendix B to 10 CFR part 30 are not aligned with the NRC's primary radiation protection regulations in 10 CFR part 20. Appendix B to 10 CFR part 30 is based upon the radiation principles from ICRP Publication 2 (1959), while the values in appendix C to 10 CFR part 20 are based upon the more risk-informed principles in ICRP recommendations (ICRP Publication 26) and methodologies (ICRP Publication 30).

In addition, the current listing of radionuclides in appendix B to 10 CFR part 30 is not well-aligned 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. However, the NRC has not updated appendix B to 10 CFR part 30 to add NARM radionuclides and their possession values.

The application of the generic default possession values in appendix B to 10 CFR part 30 for the DFA determinations of unlisted NARM radionuclides is not warranted based on risk to public health and safety. First, the types and quantities of byproduct material originally found in appendix B to 10 CFR part 30 were not developed to determine decommissioning funding. Rather, the values were initially derived from

exceptions to labeling requirements such that certain small quantities of byproduct material could be released into the sanitary sewerage or buried in soil for disposal (58 FR 67657, December 22, 1993). Second, the default values were based upon the radiation protection principles in ICRP Publication 2 (1959) that were not risk informed by research into the biological effects of ionizing radiation. Third, the default values are generic and do not reflect isotope specific possession values and their associated radiological, chemical, and physical properties. Fourth, the generic default values are set to equal the most restrictive values of the nonrisk-assigned isotopes: 0.01 µCi for alpha emitters like radium-226, and 0.1 µCi for the most restrictive values of nonalpha-bearing isotopes (iodine-129, strontium-90).

For example, for an unsealed nonalpha-emitting isotope, a licensee possessing more than 0.1 millicurie (mCi) but less than 1 mCi would be required under 10 CFR 30.35(d) to provide $225,000 in DFA. To possess more than 1 mCi of the radionuclide, 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 NARM isotopes Ge-68, gold-195, and sodium-22. Thus, the application of these generic default possession values creates regulatory burdens by requiring licensees to provide decommissioning funding that is not risk informed by the isotope specific possession values.

b) Reduces or Eliminates Exemption Requests

The NRC currently has granted a limited number of licensee-requested exemptions for medical licensees that use Ge-68/Ga-68 generators under certain conditions. These exemptions were approved in advance of pending rulemaking to generically resolve the issue. By providing a regulatory solution through rulemaking, the NRC would create a more stable framework for use by regulators, applicants, and licensees.

If the NRC does not complete this rulemaking, then the Ge-68/Ga-68 exemption requests would be reviewed on a case-by-case basis, where a licensee would need to demonstrate its unique circumstances that warrant an exemption. In addition, since many of these unlisted radionuclides are used in the medical field, if the NRC does not pursue this rulemaking, many users of these unlisted isotopes are likely to submit additional numerous requests for exemptions to the DFA requirements. The time and cost impacts from processing numerous exemption requests from DFA requirements on a case-by-case basis for the radionuclides with a half-life greater than 120 days would be very burdensome for the NRC and the Agreement States. In addition, to the extent that the agency frequently issues similar exemptions, the NRC could be viewed as not following its own regulations.

c) Unaligned Appendix Title and Purpose

Appendix B to 10 CFR part 30 is titled “Quantities of Licensed Material Requiring Labeling.” This title is not consistent with its intent and purpose. Appendix B to 10 CFR

part 30 is used solely for the purpose of calculating the required amounts of DFA. In addition, this title is the same as that of appendix C to 10 CFR part 20. Thus, this could potentially cause confusion about the appropriate appendix for labeling requirements and the appropriate appendix for decommissioning requirements. Therefore, this rule will change the title of appendix B to 10 CFR part 30 to, "Quantities of Licensed Material Used to Assess Financial Assurance for Decommissioning."

d) Unaligned Listing of Isotopes and Decommissioning Criteria

The current NRC regulations in 10 CFR 30.35 and 10 CFR 70.25 document the criteria for determining the amount of DFA required by licensees. DFA considerations only apply for radionuclides with a half-life greater than 120 days. However, the table in appendix B to 10 CFR part 30, which is used for calculating DFA costs, includes radionuclides with a half-life of 120 days or less. The disconnect between the criteria in 10 CFR 30.35 and the list of radionuclides in the table in appendix B to 10 CFR part 30 can lead to confusion about which radionuclides need to be considered when determining DFA requirements.

III. Whom Would This Action Affect and How?

The Agreement States will have 3 years to adopt the regulatory changes. The Agreement States would need to review licensee revisions to DFA estimates or DFPs.

Licensee's may need to review their DFA requirements to assess whether this rulemaking impacts them. Additionally, some licensees may need to submit updated DFA estimates or DFPs for NRC or Agreement State review.

Licensees may choose to submit a DFP under 10 CFR 30.35(e) or a certification that financial assurance for decommissioning has been provided in the amount prescribed by paragraph 10 CFR 30.35(d). The DFP requirements in 10 CFR 30.35(e) were intended for major facilities possessing large quantities of radioactive material with half-lives greater than the 120-day criterion because they require a significant decommissioning effort. The 10 CFR 30.35(e) requirements generally were not applicable for the types and quantities of radioactive material typically used by medical licensees, because such licensees normally use radionuclides with short half-lives that can decay-in-storage before disposal (10 CFR 35.92). Although medical licensees possess smaller quantities of radioactive material, they may possess unsealed radionuclides with a half-life greater than 120 days and thus may develop facility-specific decommissioning cost estimates in accordance with 10 CFR 30.35. Some licensees may find the submission of a DFP more efficient and cost effective than the certification of financial assurance for decommissioning. The review and approval of DFP under 10 CFR 30.35(e) might be resource intensive for both the licensee and the regulatory agency.

IV. Specific Requests for Comments

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

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:

Assumptions Used for Cost/Benefit Estimates

- The NRC is seeking comments on the assumptions used in developing the cost-benefit estimates. The NRC is interested in receiving information on the number of licensees affected by the rulemaking. The NRC is also interested in the effort needed to make any changes to current DFPs or DFA funding amounts, especially if an increase in decommissioning funding would be required.

- The NRC is seeking comments on possible impacts to small entities. Section 2.810, “NRC size standards,” provides specific size standards to determine whether a licensee qualifies as a small entity in its regulatory programs. The NRC is interested in the number of small entities that would be impacted by these changes, as well as the types of impacts the changes being proposed by this rulemaking would have on them.

- The NRC also is seeking comments on other benefits of the rulemaking, such as supporting advancements in science and technology, enabling uses of radioisotopes that would reduce effective doses to patients or overall costs to patients, and reducing costs to licensees who currently must develop DFPs. Please provide quantitative information on costs and benefits, if available.

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

V. Section-by-Section Analysis

Appendix B to 10 CFR Part 30—Quantities of Licensed Material Requiring Labeling.

This proposed rule would revise the title of and the table to appendix B to 10 CFR part 30, thereby also removing the footnote in the title.

§ 70.25 Financial assurance and recordkeeping for decommissioning.

This proposed rule would revise paragraphs (a)(2) and (b) to specify unsealed special nuclear material "of half-life greater than 120 days."

VI. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. This proposed rule would affect a number of "small entities" as defined by the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810). However, as indicated in the draft regulatory analysis available under the "Availability of Documents" section, the proposed amendments, if promulgated, would not have a significant economic impact on the affected small entities.

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

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

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC.

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

The NRC requests public comment on the draft regulatory analysis. The regulatory analysis is available as indicated in the "Availability of Documents" section of this document. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES caption of this document.

VIII. Backfitting and Backfitting and Issue Finality

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) does not apply to this proposed rule because this amendment does not involve any provisions that would impose backfits as defined in the backfit rule. The proposed changes to the NRC's decommissioning funding requirements for radioactive material based on the relative risk to public health and safety from different radioisotopes, including naturally occurring and accelerator-produced radioactive material will not involve backfitting or issue finality considerations. The entities subject to the revised requirements needed to implement the proposed rule are not accorded backfitting or issue finality protection. Therefore, a backfit analysis is not required.

IX. Cumulative Effects of Regulation

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

The NRC is following its Cumulative Effects of Regulation (CER) process by engaging with external stakeholders throughout this proposed rule and related regulatory activities. Opportunity for public comment is provided to the public at this proposed rule stage.

1. In light of any current or projected CER challenges, does the proposed rule's [effective date, compliance date, or submittal date(s)] provide sufficient time to implement the new proposed requirements, including changes to programs, procedures, and the facility?

2. If CER challenges currently exist or are expected, what should be done to address them? For example, if more time is required for implementation of the new requirements, what period of time is sufficient?

3. Do other (NRC or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests inspection findings of a generic nature) influence the implementation of the proposed rule's requirements?

4. Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the unintended consequences, and how should they be addressed?

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

X. Plain Writing

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

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 and Proposed Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and an environmental impact statement is not required. The basis of this determination reads as follows: The proposed action to revise NRC's decommissioning funding requirements for radioactive material based on the relative risk to public health and safety from different radioisotopes, including naturally occurring and accelerator-produced radioactive material would not lead to any increase in the effect on the environment of decommissioning activities.

The determination of this environmental assessment is that there will be no significant effect on the quality of the human environment from this action. Public stakeholders should note, however, that comments on any aspect of this environmental assessment may be submitted to the NRC as indicated under the ADDRESSES caption. The environmental assessment is available as indicated under the "Availability of Documents" section.

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and has requested comments.

XII. Paperwork Reduction Act

This proposed rule contains a new or amended collection 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 collection(s).

Type of submission: Revision

The title of the information collection: Decommissioning Financial Assurance

How often the collection is required or requested: Annually

Who will be required or asked to respond: Applicants and licensees who decommissioning financial assurance was changed due to the new table in appendix B to 10 CFR part 30.

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

An estimate of the number of annual responses:

Part 30: X

Part 70: X

The estimated number of annual respondents:

Part 30: X

Part 70: X

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

Part 30: X

Part 70: X

Abstract:

The NRC is proposing to amend its regulations for DFA for sealed and unsealed radioactive materials. The rulemaking would revise NRC's decommissioning funding requirements for radioactive material based on the relative risk to public health and safety from different radioisotopes, including naturally occurring and accelerator-produced radioactive material. The potentially affected licensees are those authorized to possess radioactive material licenses.

The NRC is seeking public comment on the potential impact of the information collection(s) 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?

2. Is the estimate of the burden of the proposed information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

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 ADAMS under Accession No. MLXXXXXXXX or can be obtained 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 submissions related to the OMB clearance package by searching on https://www.regulations.gov under Docket ID NRC-2017-0031.

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 methods:

- **Federal Rulemaking Website:** Go to https://www.regulations.gov and search for Docket ID NRC-2017-0031.

- **Mail comments to:** FOIA, Library, and Information Collections Branch, Office of the Chief Information Officer, Mail Stop: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-XXXX, 3150-XXXX), Attn: Desk Officer for the

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

Nuclear Regulatory Commission, 725 17th Street, NW, Washington, DC 20503; email: oira_submission@omb.eop.gov.

Submit comments by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC 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

The working group involved in the preparation of this proposed rule included a representative from the OAS. Early drafts of this proposed rule were provided to Agreement States for review. Comments from Agreement States were taken into consideration during the development of this proposed rule.

XIV. Coordination with the Advisory Committee on the Medical Uses of Isotopes

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

On Month, day, 2023, the NRC provided the preliminary draft proposed rule to the ACMUI for a 90-day review. The draft (ADAMS Accession No. MLXXXXXXXXX) was made public to facilitate the ACMUI review in a public forum. The ACMUI discussed the draft proposed rule at a publicly held teleconference on month, day, 2023, (conference transcripts are available in ADAMS at MLXXXXXXXXX), and provided a final report to the NRC on date (ADAMS Accession No. MLXXXXXXXXX).

XV. Compatibility of Agreement State Regulations

Under the "Agreement State Program Policy Statement" approved by the Commission on October 2, 2017, and published in the *Federal Register* on October 18, 2017 (82 FR 48535), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC, or Health and Safety (H&S). Compatibility Category A program elements are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B program elements are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program

elements in an essentially identical manner. Compatibility Category C program elements are those program elements that do not meet the criteria of Category A or B but contain the essential objectives that an Agreement State should adopt 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 should adopt the essential objectives of the Category C program elements. Compatibility Category D program elements are those program elements that do not meet any of the criteria of Category A, B, or C and, therefore, do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC program elements are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the Atomic Energy Act of 1954, as amended. These program elements should not be adopted by the Agreement States. Category H&S program elements are program elements that are required because of a particular health and safety role in the regulation of agreement material within the State and should be adopted in a manner that embodies the essential objectives of the NRC program. The portions of this proposed rule that amend appendix B to 10 CFR part 30 and 10 CFR 70.25 are a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements, and are listed in the following table.

Compatibility Table

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

Section	Change	Subject	Compatibility	
			Existing	New
Part 30				
Appendix B	Amend	[Title]	--	--
Appendix B	Amend	Quantities of…	B	B
Part 70				
70.25(a)(2) and (b)		Financial Assurance and Recordkeeping for Decommissioning	H&S	H&S

XVI. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 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 is proposing to amend its regulations for DFA for sealed and unsealed radioactive materials. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XVII. Availability of Guidance

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

The NRC will not be issuing guidance for this rulemaking.

XVIII. Public Meeting

The NRC will conduct a public meeting during the comment period for this proposed rule for the purpose of facilitating the submittal of comments and answering questions from the public on this proposed rule.

The NRC will publish a notice of the location, time, and agenda of the meeting on the NRC's public meeting website at least 10 calendar days before 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.

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
<**INSERT:** title of document>	[MLXXXXXXXXX]
SECY-23-0XXX, "Proposed Rule: Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials (RIN 3150-AK52; NRC-2017-0031)," [DATE]	[MLXXXXXXXXX]

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

Staff Requirements Memorandum for SECY-23-0XXX, "Proposed Rule: Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials (RIN 3150-AK52; NRC-2017-0031)," [DATE]	[MLXXXXXXXXX]
Annotated Comment Submissions on the Regulatory Basis: Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials (RIN 3150-AK52; NRC-2017-0031)," [DATE]	[MLXXXXXXXXX]
Management Directive 5.9, "Adequacy and Compatibility of Program Elements for Agreement State Programs," dated April 26, 2018	ML18081A070
Advisory Committee on the Medical Uses of Isotopes (ACMUI) Final Report, "Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) Final Report," August 12, 2015	ML15231A047
PRM-30-66, Naturally-Occurring and Accelerator-Produced Radioactive Materials; Notice of Docketing and Request for Comment; Consideration in the Rulemaking Process, November 27, 2020	85 FR 75959
Agreement State Program Policy Statement; Revision to Policy Statement, Correction, October 18, 2017	82 FR 46840
Agreement State Program Policy Statement, Revision to Policy Statement, October 6, 2017	82 FR 48535
PRM-30-66, Naturally-Occurring and Accelerator-Produced Radioactive Materials; Notice of Docketing and Request for Comment, August 23, 2017	82 FR 39971
Authorization for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators, July 29, 2016	ML16082A415

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

Revision of Technical Basis for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators, July 13, 2017	ML17075A487
Public Comments	ML18038A879 (package)

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-2017-0031. 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-2017-0031); 2) click the "Subscribe" link; and 3) enter an email address and click on the "Subscribe" link.

List of Subjects

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 and 70.

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

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

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

Authority: Atomic Energy Act of 1954, secs. 11, 81, 161, 181, 182, 183, 184, 186, 187, 223, 234, 274 (42 U.S.C. 2014, 2111, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

2. In 10 CFR part 30, appendix B to 10 CFR part 30 is revised to read as follows:

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

Material	Microcuries
Actinium-227	0.001
Aluminum-26	10
Americium-241	0.001
Americium-242m	0.001
Americium-243	0.001
Antimony-125	100
Argon-39	1,000
Barium-133	100
Berkelium-247	0.001
Berkelium-249	0.1
Beryllium-10	1
Bismuth-207	10
Bismuth-210m	0.1
Cadmium-109	1
Cadmium-113m	0.1
Cadmium-113	100
Calcium-41	100
Calcium-45	100
Californium-248	0.01
Californium-249	0.001
Californium-250	0.001
Californium-251	0.001
Californium-252	0.001
Carbon-14	100
Cerium-139	100
Cerium-144	1
Cesium-134	10
Cesium-135	100

Material	Microcuries
Cesium-137	10
Chlorine-36	10
Cobalt-57	100
Cobalt-60	1
Curium-242	0.01
Curium-243	0.001
Curium-244	0.001
Curium-245	0.001
Curium-246	0.001
Curium-247	0.001
Curium-248	0.001
Dysprosium-159	100
Einsteinium-254	0.01
Europium-150	1
Europium-152	1
Europium-154	1
Europium-155	10
Gadolinium-148	0.001
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

Material	Microcuries
Lead-205	100
Lead-210	0.01
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
Neptunium-236	0.001
Neptunium-237	0.001
Nickel-59	100
Nickel-63	100
Niobium-93m	10
Niobium-94	1
Osmium-194	1
Palladium-107	10
Platinum-193	1,000
Plutonium-236	0.001
Plutonium-238	0.001
Plutonium-239	0.001
Plutonium-240	0.001
Plutonium-241	0.01
Plutonium-242	0.001
Plutonium-244	0.001
Polonium-210	0.1
Potassium-40	100
Promethium-143	100
Promethium-144	10
Promethium-145	10
Promethium-146	1
Promethium-147	10
Protactinium-231	0.001
Radium-226	0.1
Radium-228	0.1

Material	Microcuries
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-228	0.001
Thorium-229	0.001
Thorium-230	0.001
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

Material	Microcuries
Titanium-44	1
Tungsten-181	1,000
Uranium-232	0.001
Uranium-233	0.001
Uranium-234	0.001
Uranium-235	0.001
Uranium-236	0.001
Uranium-238	100
Uranium-natural[2]	100
Vanadium-49	1,000
Zinc-65	10
Zirconium-93	1
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001
Any radionuclide other than alpha emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

[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 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

3. 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.

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

Section 70.21(g) also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152).

THIS PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH THE ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES. THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

Section 70.31 also issued under Atomic Energy Act sec. 57(d) (42 U.S.C. 2077(d)).

Sections 70.36 and 70.44 also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234).

Section 70.81 also issued under Atomic Energy Act secs. 186, 187 (42 U.S.C. 2236, 2237).

Section 70.82 also issued under Atomic Energy Act sec. 108 (42 U.S.C. 2138).

Source: 21 FR 764, Feb. 3, 1956, unless otherwise noted.

§ 70.25 [Amended]

4. In § 70.25:

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), 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,”.

Dated: <Month XX, 20XX>.

For the Nuclear Regulatory Commission.

<**INSERT:** Name>,

<**INSERT:** Title of signing official>.