

**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. This proposed rule would revise 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. The potentially affected licensees are those authorized to possess licensed radioactive material. The NRC plans to hold a public meeting to promote full understanding of this proposed rule and facilitate public comments.

**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 NRC 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](mailto:Dawn.Forder@nrc.gov). For technical questions contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

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

- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 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.

**FOR FURTHER INFORMATION CONTACT:** Gregory Trussell, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-6244, email: [Gregory.Trussell@nrc.gov](mailto:Gregory.Trussell@nrc.gov) and Adam Schwartzman, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-8172, and email: [Adam.Schwartzman@nrc.gov](mailto:Adam.Schwartzman@nrc.gov),

Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

**SUPPLEMENTARY INFORMATION:**

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**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](mailto: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:** 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](mailto: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 proposed rule would adjust decommissioning financial assurance (DFA) requirements for sealed and unsealed radioactive material so that licensees would not have to apply the appendix's default values to calculate decommissioning funding requirements. Thus, the rule would set appropriate limits for important industrial technologies and current and emerging medical uses. This section discusses the evolution of the existing regulatory framework to provide context for the changes.

### **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 Commission papers and staff requirements memorandums (SRMs), contractor reports, *Federal Register* notices, a generic environmental impact statement,

public meetings, and comment analysis.<sup>1</sup> The purpose of the rule was to assure that, at the 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 section 30.35 of title 10 of the *Code of Federal Regulations* (10 CFR), “Financial assurance and recordkeeping for decommissioning,” 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 to determine whether a decommissioning funding plan (DFP) was needed. The regulation in § 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**

On December 22, 1993, the NRC redesignated the original appendix C to part 20 to the newly created appendix B to part 30 (58 FR 67657). In turn, it revised §§ 30.35

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<sup>1</sup> 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-78-13 ‘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).

and 70.25 to replace references to “appendix C to 10 CFR part 20” with references to “appendix B to 10 CFR part 30.”

As a result, the values in appendix B to 10 CFR part 30 continued to be based upon International Commission on Radiological Protection (ICRP) Publication 2. The NRC decided not to conform the values in appendix B to 10 CFR part 30 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**

The NRC and Agreement States collectively regulate 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.

#### *a. NRC Regulatory Program*

The NRC’s regulations in § 30.35 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 § 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 §§ 30.35(a)(1) and 70.25(a)(2), DFPs must be submitted when unsealed radionuclide concentrations exceed  $1 \times 10^5$  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  $1 \times 10^{12}$  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 §§ 30.35(d) and 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 this proposed rule, the NRC would add the seven plutonium radionuclides with half-lives greater than 120 days to 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, §§ 70.25(a)(2) and (b) 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.

#### **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 part 30, which means that they are subject to requirements to provide DFA if amounts exceed default values. Germanium (Ge)-68 and gallium (Ga)-68, are of particular concern to those in the medical field, because these isotopes were not listed and the default values resulted in overly conservative decommissioning financial assurance requirements. 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<sup>2</sup> 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

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<sup>2</sup> 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.

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 Medical Uses of Isotopes (ACMUI) issued the “Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) Final Report,” 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. Therefore, 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, and July 13, 2017, 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 can be completed that would provide a generic regulatory solution.

*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 material (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.

On August 23, 2017, the NRC published a document in the *Federal Register*, which docketed the petition (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 supported the rulemaking. One commenter requested a generic exemption

that can only be provided by rulemaking. No commenters opposed rulemaking, but one letter, while supporting a rulemaking for medical licensees, indicated that rulemaking could result in exempting industrial uses from the Atomic Energy Act of 1954, as amended, 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, "Petition for Rulemaking and Rulemaking Plan on Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Material" and Associated SRM-SECY-19-0125*

The NRC sought Commission approval to initiate rulemaking in response to the OAS petition. As discussed in SECY-19-0125, this proposed rule 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.
- 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 NRC published a document in

the *Federal Register* 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. Pre-rulemaking: Regulatory Basis*

For this rulemaking, NRC developed a regulatory basis (ADAMS Accession No. ML21235A480) that summarized the current regulatory framework, described the regulatory issues, evaluated alternatives, and presented a recommendation for revising appendix B to 10 CFR part 30. On April 28, 2022, NRC published a document in the *Federal Register* requesting public comment on the regulatory basis supporting this proposed rule (87 FR 25157).

The regulatory basis proposed 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, because that alternative addresses the issues as described in the petition as well as direction by the Commission (Staff Requirements Memorandum-SECY-19-0125). The regulatory basis also included 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 into one or more comments.

**Table 1—ADAMS References for Public Comment Submissions on the Regulatory Basis**

<b>Comment Submission ID</b>	<b>Commenter</b>	<b>ADAMS Accession Number</b>
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	ML22180A033
8	Brady Jens	ML22180A034

The NRC reviewed and summarized the comments and organized them by category. The following section presents the NRC's response to these comments.

**Comments and Responses**

*Support for the Proposed Rule*

**Comment summary:** Commenter 7 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 (EPA) 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:** Commenter 3 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:** Commenter 6 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 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 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, would incorporate these newer nuclides. If amended, the proposed appendix B to 10 CFR part 30 would address concerns related to DFA 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 Decommissioning Financial Assurance*

**Comment summary:** Commenter 2 commented that the NRC should pursue Alternative 5 as presented in the regulatory basis. Alternative 5 addresses the immediate concerns raised by the petitioner (Alternative 2) and suggests a second rulemaking to address concerns with the existing regulations regarding DFA requirements in § 30.35.

**Comment summary:** Commenter 5 commented that the NRC should consider Alternative 5. 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 should pursue an additional rulemaking for a more modern, risk-informed approach for developing and maintaining an up-to-date DFP. The commenter stated that Alternative 5 (combination of Alternatives 2 and 4) combines the benefits of accomplishing an expedited rulemaking while also incorporating forward-looking, extensive rulemaking.

**NRC Response:** The NRC acknowledges comments that support a complete revision of the process for assessing decommissioning funding costs (Alternative 4). The regulatory basis for this rulemaking concluded that a complete revision of DFA would not



be cost effective for the NRC, Agreement States, and licensees, resulting in an estimated net cost of (\$8,718,000), undiscounted (see page 26 of the regulatory basis). In addition, a complete process revision would fall outside the scope of the rulemaking directed by the Commission. The NRC may consider a complete revision of the DFA regulations as identified in Alternative 4 (i.e., developing an entirely new process for determining DFA) in a future rulemaking effort.

#### *Cost to Licensees*

**Comment summary:** Commenter 6 commented that the current NRC regulatory framework for DFA has put an undue hardship on a potential license applicant. Due to the hardship, the license applicant or 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 summary:** Commenter 1 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 summary:** Commenter 8, 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 summary:** Commenter 4 commented that decommissioning costs hurt the ability of a small business to remain viable. They asked for consideration for alternative measures when a small business returned the Ge-68/Ga-68 generators while also maintaining the safety of employees and the community.

**NRC Response:** The NRC disagrees in part with these comments. Although the change to the table in appendix B to 10 CFR part 30 will affect the applicability of § 30.35 certification requirement, NRC applicants or licensees always have the option to submit a DFP in support of the financial assurance amount. While in rare cases the financial assurance required for a DFP may increase, it is more likely to provide regulatory relief by lowering the DFA required for licensees possessing certain materials or devices like Ge-68/Ga-68 generators. However, the NRC agrees that that additional decommissioning funding costs may affect the viability of a small business. The NRC welcomes comments on the initial regulatory flexibility analysis, as provided in the draft regulatory analysis, with regard to the impact of the proposed requirements on small entities.

*Exemptions from Decommissioning Funding Plan and Decommissioning Financial Assurance Requirements for Ge-68/Ga-68 Generators*

**Comment summary:** Commenter 1 commented that the NRC should exempt licensees from the requirements in § 30.35 for DFA for Ga-68 generators. The commenter provided details as to the cost of obtaining and maintaining decommissioning financial assurance.

**Comment summary:** Commenter 8 commented that the NRC should exempt licensees from the requirements in § 30.35 for DFA for Ga-68 generators.

**Comment summary:** Commenter 5 commented that the NRC should exempt generators used for medical use or in research from DFPs.

**Comment summary:** Commenter 7 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 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 this rulemaking that would 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 could pursue 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 to the table with a specific value. These values match up to the values in the July 29, 2016, memorandum. Once the rule becomes effective the NRC would need to address the status of the July 29, 2016, memorandum. However, the NRC notes that exempting Ge-68/Ga-68 generators or medical isotope generators more generally from requirements for DFA is outside the scope of the current proposed rule.

#### *Threshold Levels in Proposed New Appendix B are Too High*

**Comment summary:** Commenter 2 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 1 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 § 30.35 was last updated in 2003 (68 FR 57335; October 3, 2003). The fixed dollar amounts for decommissioning financial assurance listed in § 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 current financial assurance threshold for cobalt-60 and cesium-137 sealed sources is one million and ten million curies, respectively. 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, “Results of the Byproduct Material Financial Scoping Study,” the NRC recommended that the financial assurance requirements in § 30.35 be expanded to include all Category 1 and 2 byproduct material radioactive sealed sources tracked in the National Source Tracking System.

On December 8, 2021, the Commission approved the staff’s recommendation, “Staff Requirements – SECY-16-0115 – Rulemaking Plan on Financial Assurance for

Disposition of Category 1 and 2 Byproduct Material Radioactive Sealed Sources,” to initiate a rulemaking to expand the NRC's financial assurance requirements in § 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. To access information regarding the ongoing rulemaking, “Financial Assurance Requirements for Category 1 and 2 Byproduct Material Sealed Sources” on the federal rulemaking website, [www.regulations.gov](http://www.regulations.gov), search for Docket ID NRC- 2022-0106. The NRC tracks the status of all planned rulemaking activities on its public website, <https://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/active/ruleindex.html>.

### **III. Discussion**

#### **A. What Action Is the NRC Proposing?**

The NRC would revise the current table in appendix B, “Quantities of Licensed Material Requiring Labeling,” to 10 CFR part 30 by replacing it with 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. 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. The default values would be set to equal the lowest values of the listed radionuclides: 0.001 microcuries ( $\mu\text{Ci}$ ) for alpha-emitting radionuclides like uranium-235, and 0.01  $\mu\text{Ci}$  for the most restricted non-alpha-emitting radionuclides (e.g., lead-210). Finally, 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 a

result of these changes, licensees, the NRC, and the Agreement States would have an up-to-date table with more risk-informed values for use when assessing DFA.

## **B. Why Is the NRC Taking This Action Now?**

### *a. PRM 30-66 Petition for Rulemaking; Revision of 10 CFR 30 Appendix B*

The NRC is proposing a revision to the 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.” This proposed rule 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 § 30.35, “Financial assurance and recordkeeping for decommissioning,” and § 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, 1977) and methodologies (ICRP Publication 30, 1982).

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 NRC has determined that 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 needed 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 for determining 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, which were established prior to more current research into the biological effects of ionizing radiation, which now considers the radiosensitivity of specific organs. 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 non-risk-assigned isotopes: 0.01  $\mu\text{Ci}$  for alpha emitters like uranium-233, and 0.1  $\mu\text{Ci}$  for the most restrictive values of non-alpha-bearing isotopes (strontium-90).

For example, for an unsealed non-alpha-emitting isotope, a licensee possessing more than 0.1 millicurie (mCi) but less than 1 mCi would be required under § 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. Therefore, the application of the current generic default possession values creates regulatory burdens by requiring licensees to provide decommissioning funding that is not commensurate with the risk of isotope-specific possession values.

*b. Reduces or Eliminates Exemption Requests*

The NRC 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 this rulemaking. By providing a regulatory solution through rulemaking, the NRC would create a more stable regulatory framework for applicants, licensees, and regulators.

If the NRC does not complete this rulemaking, then the Ge-68/Ga-68 exemption requests would continue to be reviewed on a case-by-case basis, where a licensee would need to demonstrate its unique circumstances that warrant granting 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 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 burdensome for the applicant or licensee, the Agreement States, and the NRC. 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 inconsistent 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. This could potentially cause confusion about the appropriate appendix for labeling requirements and the appropriate appendix for decommissioning requirements. 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.”

*d. Unaligned Listing of Isotopes and Decommissioning Criteria*

The current NRC regulations in §§ 30.35 and 70.25 document the criteria for determining the amount of DFA required by licensees. These 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 some radionuclides with a half-life of 120 days or less. The disconnect between the criteria in § 30.35 and the list of radionuclides in the table in appendix B to 10 CFR part 30 can cause confusion about which radionuclides need to be considered when determining DFA requirements. Therefore, this proposed rule would 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.

**C. Whom Would This Action Affect and How?**

Stakeholders requested 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. For example, the currently unlisted gallium-68 (Ga-68) radionuclide is vitally important in the early detection and treatment of liver and pancreatic cancers; these types of cancers are hard to diagnose and metastasize quickly through the body. The proposed possession values also would allow for the development of other emerging medical and industrial technologies. Applicants and licensees seeking to pursue new devices would benefit from the provisions in this proposed rule.

Under current requirements, NRC part 30 licensees may choose to submit 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). The DFP requirements in § 30.35(e) were originally thought to be more relevant 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 § 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 (§ 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 could develop facility-specific decommissioning cost estimates in accordance with § 30.35. 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 efficient and cost effective than the certification of financial assurance for decommissioning. The proposed changes to radionuclide values in

appendix B to part 30 could increase or decrease the amount required for decommissioning financial assurance for an individual NRC part 30 licensee. After evaluating the impact of the proposed provisions to their decommissioning financial assurance mechanism, a licensee may be required to make revisions that lead to additional costs. However, NRC expects that most part 30 licensees will benefit from these changes (for details, see the regulatory analysis, Table 3).

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 Part 30 will not impact part 70 licensees, as their possession quantities exceed the threshold identified in § 70.25(d).

The Agreement States would have 3 years to adopt the regulatory changes. Agreement State licensees may need to update their financial assurance for decommissioning in accordance with their states' regulations. The Agreement States would need to review licensee revisions to DFA estimates or DFPs.

At the time the final rule is effective, all licensees covered by this rule will be required to review the updated table in appendix B to part 30 to determine whether changes are needed. Licensees that would be required to 1) now have DFA or DFP or 2) increase their DFA amounts will be required to implement these changes by the compliance date. Licensees that 1) no longer require DFA or DFP or 2) could decrease their DFA may voluntarily do so at their discretion after the effective date of the rule. Licensees would request approvals to change 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.

#### **IV. 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 the assumptions used in developing the cost-benefit estimates. 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. 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.
- The NRC is seeking comments on other benefits of this proposed rule, 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.

The NRC also is seeking comments on the errata to NUREG-1757, Volume 3, Revision 1.

## **V. Section-by-Section Analysis**

The following paragraphs describe the specific changes in this proposed rule:

### *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, and it would also remove the footnote from the title.

### *§ 70.25 Financial assurance and recordkeeping for decommissioning.*

In § 70.25, this proposed rule would revise paragraphs (a)(2) and (b) to specify unsealed special nuclear material “of half-life greater than 120 days.”

## **VI. Initial Regulatory Flexibility Analysis**

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), as amended by the Small Business Regulatory Enforcement Fairness Act, requires that each Federal agency consider the impact of its rulemakings on small entities and evaluate alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition. In essence, the RFA requires that each agency analyze the impact of the rulemaking on different size entities, estimate the effectiveness of the regulatory action in addressing the source of the problem, and consider alternatives that would minimize compliance costs. The NRC has prepared an initial regulatory flexibility analysis of the impact of this proposed rule on small entities. As required by Section 604 of the RFA, the NRC will prepare a final regulatory flexibility analysis for this action as part of the final rule. The final regulatory flexibility analysis will address the issues raised by public comments on the initial regulatory flexibility analysis.

The proposed rule would affect 440 licensees. The NRC estimates that 6 percent of all NRC and Agreement State licensees may qualify as small business entities as defined by 10 CFR 2.810. This equates to 27 small entities. For the purpose of this rulemaking, the NRC assumes "significant" impact when the revenues or costs of any class of affected entities change by more than 3 to 5 percent in 5 years. The NRC does not expect any of the small entities will be affected to the extent set by these criteria. In fact, the proposed rule would have an estimated \$2,257 (\$933,000/440 impacted licensees at seven percent net present value) averted net cost per licensee for all impacted licensees. The NRC believes that the selected alternative reflected in this

proposed rule is the least burdensome, most flexible alternative that would accomplish the NRC's regulatory objective. There is no significant economic impact on a substantial number of small entities. However, applicants will experience averted costs by reducing the number of needed financial assurance instruments, (e.g., Surety bond, Letter of Credit, and Trust Agreement), and the cost of obtaining these instruments. The initial regulatory flexibility analysis is provided in the draft regulatory analysis.

The NRC is seeking public comment on the potential impact of the proposed rule on small entities. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how the proposed regulation will affect them and how the regulation may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting public health and safety and common defense and security. Comments on how the regulation could be modified to take into account the differing needs of small entities should specifically discuss:

(a) The size of the business and how the proposed regulation would result in a significant economic burden upon it as compared to a larger organization in the same business community;

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

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation was modified as suggested by the commenter;

(d) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations as opposed to providing special advantages to any individuals or groups; and

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

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 rule would result in total net averted costs to the NRC, Industry, and Agreement States of \$813,000 using a seven percent discount rate, making the overall proposed rule cost beneficial. The analysis examines the costs and benefits of the alternatives considered by the NRC. 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 regulatory analysis may be submitted to the NRC as indicated under the ADDRESSES caption of this document.

## **VIII. 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. Part 70 licensees that have backfit protection are not impacted by this rule. Each of these licensees is already required to submit a site-specific financial assurance plan because their authorized possession limits already exceed the table values. Therefore, a backfit analysis is not required. Part 30 does not have a backfit provision. The costs and benefits of this rulemaking for Part 30 licensees is included in the regulatory analysis for this rulemaking.

## **IX. Cumulative Effects of Regulation**

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, how will a compliance date of three years from the proposed effective date of the rule affect the existing licensees ability to manage existing and potential new requirements, including whether the compliance date provides sufficient time to implement the new requirements and changes to programs and procedures?
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. What 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. 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**



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 from 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.

## **XII. Paperwork Reduction Act Statement**

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 for Sealed and Unsealed Radioactive Materials

*How often the collection is required or requested:* Once and 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.

*An estimate of the number of annual responses:*

147

*The estimated number of annual respondents:*

147

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

7,880 (7,750 hours reporting + 130 hours recordkeeping)

*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) supporting statement is available in ADAMS under Accession No. ML23032A385 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](mailto: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 (3150-0017), Attn: Desk Officer for the Nuclear

Regulatory Commission, 725 17th Street, NW, Washington, DC 20503; email:

[oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).

Submit comments by **[INSERT DATE 30 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 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 Organization of Agreement States (OAS). In a January 5, 2023, the staff shared the draft proposed rule with the OAS, for information only (non-public letter). Comments from Agreement States will be taken into consideration during the development of the final rule.

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

On January 13, 2023, the NRC provided the preliminary draft proposed rule to the ACMUI for a 90-day review. The draft was made public to facilitate the ACMUI review in a public forum. The ACMUI established a subcommittee to review and

comment on the draft proposed rule. The subcommittee discussed their report on the draft proposed rule at a publicly held teleconference on May 15, 2023, and the report was unanimously approved by the full Committee. The final report was provided to the NRC on May 17, 2023.

## **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

Section	Change	Subject	Compatibility	
			Existing	New
<b>Part 30</b>				
Appendix B	Amend	Appendix B—Quantities of Licensed Material Used to Assess Financial Assurance for Decommissioning	B	B
<b>Part 70</b>				
70.25(a)(2) and (b)	Amend	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**

The NRC has reviewed the guidance that licensees use to implement the requirements that will be revised by this rulemaking activity. The proposed changes to the values in the tables do not affect the use of the guidance, so no new or modified guidance is needed. Conforming changes to the tables in the guidance (which duplicates the rule) will be made at the next revision. Staff plans to issue an errata to update attachments 1 and 2 to Appendix A of Volume 3 of NUREG-1757, Revision 1.

### **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
SECY-23-0XXX, "Proposed Rule: Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials (RIN 3150-AK52; NRC-2017-0031)," [DATE]	ML23010A137
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]	[MLXXXXXXXXXX]
Advisory Committee on the Medical Uses of Isotopes (ACMUI), Subcommittee on the Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials, Final Report, May 17, 2023	ML23136A458
ERRATA – NUREG-1757, Vol. 3, Rev. 1, [DATE]	[ML23180A050]
Management Directive 5.9, "Adequacy and Compatibility of Program Elements for Agreement State Programs," April 26, 2018	ML18081A070
Staff Requirements for SECY-16-0115, "Rulemaking Plan on Financial Assurance for Disposition of Category 1 and 2 Byproduct Material Radioactive Sealed Sources," December 8, 2021	ML21342A032
SECY-16-0046, "Results of the Byproduct Material Financial Scoping Study," April 7, 2016	ML16068A202
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, Petition for Rulemaking; Revision of 10 CFR 30 Appendix B, April 14, 2017	ML17173A063



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
SECY-19-0125, "Petition for Rulemaking and Rulemaking Plan on Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Material" December 17, 2019	ML18292A479
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
RCPD-23-001-Availability of Proposed Rule Language For "Decommissioning Financial Assurance For Sealed and Unsealed Radioactive Materials" January 5, 2023 (non-public)	ML22335A575
Authorization for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators, July 29, 2016	ML16082A415
Revision of Technical Basis for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators, July 13, 2017	ML17075A487
Regulatory Basis for Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Materials, April 2022	ML21235A480
Public Comments on PRM 30-66, Naturally-Occurring and Accelerator-Produced Radioactive Materials	ML18038A879 (package)
Office of Management and Budget Supporting Statement, April 2023	ML23032A385
Final Rule: Financial Assurance for Materials Licensees, October 3, 2003	68 FR 57335
Plain Language in Government Writing, June 10, 1998	63 FR 31883
Final Rule: Standards for Protection Against Radiation; Clarification, August 15, 1994	59 FR 24018

Final Rule: Standards for Protection Against Radiation; Removal of Expired Material, December 22, 1993	58 FR 67657
Final Rule: Standards for Protection Against Radiation, May 21, 1991	56 FR 23360
Final Rule: General Requirements for Decommissioning Nuclear Facilities, June 27, 1988	53 FR 24018

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### **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 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.

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:

**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. 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**

<b>Material</b>	<b>Microcuries</b>
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
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
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
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 <sup>1</sup>	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-232	0.001
Uranium-233	0.001
Uranium-234	0.001
Uranium-235	0.001
Uranium-236	0.001
Uranium-238	100
Uranium-natural <sup>2</sup>	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

<sup>1</sup> Based on alpha disintegration rate of Th-232, Th-230, and their daughter products.

<sup>2</sup> 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 is revised 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]**

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) 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”.

Dated: <Month XX, 20XX>.

For the Nuclear Regulatory Commission.

Brooke P. Clark,  
Secretary of the Commission.