



# RULEMAKING ISSUE

## (Notation Vote)

July 24, 2023

SECY-23-0062

FOR: The Commissioners

FROM: Daniel H. Dorman  
Executive Director for Operations

SUBJECT: PROPOSED RULE: DECOMMISSIONING FINANCIAL ASSURANCE  
FOR SEALED AND UNSEALED RADIOACTIVE MATERIALS (3150-  
AK52; NRC-2017-0031)

PURPOSE:

The purpose of this paper is to obtain Commission approval to publish in the *Federal Register* the enclosed proposed rule (Enclosure 1). The proposed rule would amend the regulations for decommissioning financial assurance (DFA) for sealed and unsealed radioactive materials in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." The rulemaking would revise the U.S. Nuclear Regulatory Commission's (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.

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Enclosure 3 transmitted herewith contains Official Use Only - Sensitive Internal Information. When separated from Enclosure 3 this transmittal document is decontrolled.

## DISCUSSION:

### Overview of Proposed Changes to the U.S. Nuclear Regulatory Commission Regulations

The staff proposes to revise the existing table of “Quantities of Licensed Material Requiring Labeling” in Appendix B to 10 CFR Part 30 by replacing it with the table in Appendix C to 10 CFR Part 20. This would add radionuclides not currently listed in Appendix B to 10 CFR Part 30. In addition, the NRC would remove all radionuclides with a half-life of 120 days or less from Appendix B to 10 CFR Part 30, since these radionuclides are not considered when developing DFA. The proposed rule would set the default values to equal the lowest values of the listed radionuclides: 0.001  $\mu\text{Ci}$  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 rulemaking would change the title of the table in Appendix B to 10 CFR Part 30 to reflect its current use for DFA from “Quantities of Licensed Material Requiring Labeling” to “Quantities of Licensed Material Used to Assess Financial Assurance for Decommissioning.” These changes would provide licensees, the NRC, and Agreement States with an up-to-date table with more risk-informed values for use when assessing DFA.

The proposed rule would include many radionuclides used in existing and emerging medical and industrial applications that are not currently listed in Appendix B to 10 CFR Part 30. Some isotopes require significant DFA that is not aligned with the risk or costs for decommissioning. The draft proposed rule would address this concern. For example, one unlisted radionuclide, germanium-68 (Ge-68), is of particular concern to those in the medical field, as it is used to produce gallium-68-labeled (Ga-68) radiopharmaceuticals. These are vitally important in medical diagnostics and treatment.

The staff 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. Should this rulemaking be finalized, these exemptions would continue to be effective subject to the conditions on the exemptions.

### Regulatory Analysis

The NRC’s analysis demonstrates that the proposed requirements, if issued by final rule, would result in a net benefit to industry of approximately \$993,000, and a net cost to the NRC of approximately (\$202,000) using a seven percent discount rate. The net benefit to the Agreement States is approximately \$22,000 using a seven percent discount rate. Relative to the No-Action alternative, the proposed rule results in a net benefit of approximately \$813,000 (assuming a seven percent discount rate) or \$1,611,000 (assuming a three percent discount rate), making the proposed rule overall cost beneficial.

### Stakeholder Engagement

The NRC held a public meeting on January 7, 2021, to obtain stakeholder input on the regulatory approaches for DFA requirements for sealed and unsealed radioactive material (Agencywide Documents Access and Management System Package Accession No. ML21026A339). During the public meeting, the NRC discussed regulatory issues related to the current DFA requirements and specific radionuclides that are not listed in Appendix B to 10 CFR Part 30. Approximately 105 people attended the meeting, including a representative from the Organization of Agreement States (OAS) and members of the public representing licensees (medical community and researchers) and the Agreement States.

In general, the meeting participants supported the rulemaking option recommended by staff, noting that updating Appendix B to 10 CFR Part 30 to include radionuclides not currently listed would help with DFA funding by eliminating the need to use default values, which are unnecessarily restrictive.

On November 10, 2021, the NRC issued a Radiation Control Program Director (RCPD) letter (RCPD-21-008) to all the Agreement State Radiation Control Program Directors, informing them of the opportunity to provide comments on the regulatory basis. The States of Arkansas and Wisconsin, along with the OAS Board, provided comments, which the staff considered in the development of the regulatory basis.

On April 28, 2022, the NRC published a *Federal Register* notice requesting public comment on the regulatory basis that supports this draft proposed rule (87 FR 25157). The regulatory basis summarized the current regulatory framework, described the regulatory issues, evaluated alternatives, and presented a recommendation for revising Appendix B to 10 CFR Part 30. 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), (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 for developing the proposed rule as it provides specific possession values for radionuclides not currently listed in Appendix B to 10 CFR Part 30, which addressed both the issues as described in PRM-30-66, "Request of the Organization of Agreement States for the NRC to Amend Appendix B, 'Quantities of Licensed Material Requiring Labeling',"<sup>1</sup> as well as the direction of the Commission in 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 on the NRC's initial assumptions regarding the qualitative and quantitative costs and benefits of the potential rulemaking, as well as on alternatives to the current recommended approach. The NRC received a total of eight comment submissions on the regulatory basis. Three commenters supported the NRC's recommended rulemaking option. Two other commenters supported the staff's recommendation but commented that additional rulemaking was needed to incorporate development of a new methodology based on decommissioning risk factors. Four commenters requested decommissioning financial plan exemptions for medical use. Several of the commenters expressed concerns that the current regulations have a strong impact on licensee costs. The staff considered the comments in the development of the proposed rule. For more detail on the comments and the NRC's responses please see section II, "Background," of the proposed rule.

In a January 5, 2023, meeting, the staff shared the draft proposed rule (RCPD-23-001) with the OAS, for information only. The NRC staff presented the Decommissioning Financial Assurance proposed rule to the OAS members during a government-to-government meeting on Wednesday, February 1, 2023. Staff presented background on the rule, details on the staff's

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<sup>1</sup> The NRC is taking this action in response to a petition for rulemaking (PRM-30-66) submitted by the OAS on April 14, 2017, requesting that the NRC provide specific possession values for NARM radionuclides not currently listed in appendix B to 10 CFR part 30. See the Commission disposition on the PRM on November 27, 2020 (85 FR 75959).

approach to address the OAS petition and Commission's direction on the rulemaking, and the NRC's plans for engaging OAS in the rulemaking. The meeting was attended by 154 people, most of whom were members of OAS and their board, including the OAS chairperson. Attendees focused mainly on clarifying what is being addressed by the rulemaking. On February 13, 2023, staff received confirmation from the OAS Board that there was no need to formally provide the DFA proposed rule for review and comment to Agreement States before the public comment period.

The NRC staff plans to hold a public meeting during the comment period for the proposed rule.

### Implementation Guidance

The NRC has reviewed NUREG-1757, Volume 3, Revision 1, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," 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.

### Backfitting and Issue Finality Considerations

The NRC has determined that the backfit rule (10 CFR 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 assurance requirements for radioactive material are based on the relative risk to public health and safety from different radioisotopes, including naturally occurring and accelerator-produced radioactive material, and 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.

### RECOMMENDATION:

The staff recommends that the Commission approve the enclosed proposed rule for publication in the *Federal Register*.

If the Commission approves publication of the proposed rule, the staff will complete the following activities:

1. The staff will publish the proposed rule in the *Federal Register* for a 75-day public comment period.
2. The staff will submit information collection requirements to the Office of Management and Budget for its review and approval on or immediately after the date of publication of the proposed rule in the *Federal Register*.
3. The Office of Congressional Affairs will inform the appropriate congressional committees.

4. The staff will make publicly available the draft regulatory analysis for the proposed rule.
5. The staff will hold a public meeting during the comment period for the proposed rule.

COORDINATION:

The Office of the General Counsel reviewed this package and has no legal objection to the publication of the proposed rule. The Office of the Chief Financial Officer reviewed this package and has no concerns with the estimated resources in Enclosure 3. The Advisory Committee on the Medical Uses of Isotopes has reviewed the proposed rule and recommends that the staff should proceed with the rulemaking package.

Daniel H.  
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Executive Director  
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Enclosures:

1. Proposed Rule FRN for  
Decommissioning Financial  
Assurance for Sealed & Unsealed  
Radioactive Materials
2. Proposed Rule Regulatory Analysis  
for Decommissioning Financial  
Assurance for Sealed & Unsealed  
Radioactive Materials
3. Proposed Rule OUO Estimated Resources  
for Decommissioning Financial Assurance  
for Sealed & Unsealed Radioactive  
Materials Estimated Rulemaking Resources  
(non-public)

SUBJECT: PROPOSED RULE: DECOMMISSIONING FINANCIAL ASSURANCE FOR  
 SEALED AND UNSEALED RADIOACTIVE MATERIALS (3150-AK52; NRC-2017-0031)  
 DATED: July 24, 2023

**ADAMS Accession Number: ML23010A137 (package) ML23010A168 (Paper)**

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