



POLICY ISSUE **(Notation Vote)**

December 17, 2019

SECY-19-0125

FOR: The Commissioners

FROM: Margaret M. Doane
Executive Director for Operations

SUBJECT: PETITION FOR RULEMAKING AND RULEMAKING PLAN ON
DECOMMISSIONING FINANCIAL ASSURANCE REQUIREMENTS FOR
SEALED AND UNSEALED RADIOACTIVE MATERIAL (PRM-30-66;
NRC-2017-0159)

PURPOSE:

This paper seeks Commission approval to initiate rulemaking in response to a petition for rulemaking (PRM) by the Organization of Agreement States (OAS). The U.S. Nuclear Regulatory Commission (NRC) received this PRM on April 14, 2017, and docketed it as PRM-30-66 (Agency-wide Document Access and Management System (ADAMS) Accession No. ML17173A063). The petition requests the NRC to provide specific possession values for radioisotopes that are not currently listed in Appendix B to Title 10, *Code of Federal Regulations* (CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," so that licensees using these isotopes would not have to apply the Appendix's default values to calculate decommissioning funding requirements. The values in Appendix B are used only to calculate an affected Part 30 or Part 70 licensee's decommissioning funding requirement.

SUMMARY:

The petition describes concerns with the current requirement to use generic default values for determining decommissioning funding requirements for unlisted isotopes. The staff has evaluated the petition and requests the Commission's approval to initiate a rulemaking to

CONTACT: Robert MacDougall, NMSS/REFS
301-415-5175

Enclosure 2 transmitted herewith contains
Official Use Only – Sensitive Internal
Information. When separated from the
enclosure, this paper is decontrolled.

amend Appendix B to add unlisted isotopes and assign them risk-informed specific possession values that result in decommissioning funding requirements that better reflect expected costs. In making these changes, the staff would also re-set existing values for listed isotopes using the same method to ensure that all listed values are consistently risk-informed. The staff has identified two potential approaches to conducting the rulemaking and would seek public input during the rulemaking process on the more effective approach, considering opportunities for identifying and incorporating transformative changes.

In addition to providing more risk-informed possession values, the proposed rulemaking would provide an opportunity to enhance the regulatory framework for naturally-occurring and accelerator-produced radioactive material (NARM). The rulemaking would also largely eliminate the cost of continuing to conduct exemption reviews for the materials proposed to be added to Appendix B, and would establish a stronger regulatory framework for supporting new technologies. These issues do not raise health and safety or common defense and security concerns. Rather, the rulemaking would address inefficiencies related to decommissioning funding requirements. The staff has identified a mitigative concept that may avoid an unwarranted increase in some licensees' financial obligations for decommissioning under either of the two candidate methods for setting Appendix B possession values.

BACKGROUND:

The OAS petition asserts that without new possession values for isotopes not listed in 10 CFR Part 30, Appendix B, "regulators are forced to evaluate new products against these [default Appendix B] criteria and apply overly burdensome financial assurance obligations or to evaluate case by case [sic] special exemptions." Because of the need for exemptions, "[t]he OAS believes that patient health and safety is being compromised due to licensing delays of important diagnostic and therapeutic products that utilize radioisotopes not listed in the 10 CFR 30 Appendix B table. ... Further, development of new products could be discouraged due to these obstacles, diminishing the possibility of new innovative and beneficial options in both medical and industrial applications." Citing the delay in obtaining exemptions for germanium-68 (Ge-68) generators of the medical isotope Gallium-68 (Ga-68) as an example, the OAS petition states that "rather than issuing exemptions on a case by case [sic] basis, the more appropriate way to address the inconsistency in Appendix B is to amend it to add appropriate nuclides and their corresponding activities." The petitioner also notes that the NRC did not update Appendix B to add NARM after Congress added it to the definition of byproduct material under NRC regulatory responsibility in the Energy Policy Act of 2005.¹ Several recent radiopharmaceuticals are based on accelerator-produced isotopes.

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 December 6, 2017, and the agency received 20 comment letters. Fifteen explicitly supported

¹ Section 170H(e), Public Law 109-58 (42 USC §13201 et seq.), signed into law August 8, 2005. To implement its Energy Policy Act authority for discrete sources of NARM, the NRC conducted a comprehensive rulemaking, known as the NARM rule, in 2007, but did not update Appendix B to add listings and possession values for NARM. See 72 FR 55864, "Requirements for Expanded Definition of Byproduct Material: Final Rule," October 1, 2007.

rulemaking, and one requested a generic exception that only rulemaking can provide.² 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 regulation under the guise of a medical purpose.³ Five commenters identified 10 isotopes⁴ whose uses have been adversely affected by not being listed in Appendix B.

On April 25, 2018, the Petition Review Board for the PRM unanimously approved the staff recommendation to consider it in rulemaking. The Petition Review Board also noted that Appendix B's current title does not reflect its purpose and that many of its listed isotopes are not subject to decommissioning funding requirements. The Petition Review Board concluded that rulemaking in response to the PRM presented an opportunity to correct those defects and make the Appendix's default values for unlisted isotopes more risk-informed.

DISCUSSION:

In the staff requirements memorandum for SECY-15-0129, "Commission Involvement in Early Stages of Rulemaking," dated February 3, 2016, the Commission approved development and submission of a streamlined rulemaking plan in the form of a SECY paper to request Commission approval for initiating all rulemakings not already explicitly delegated to the staff (ADAMS Accession No. ML16034A441). Accordingly, a rulemaking plan which follows the Commission-approved template (ADAMS Accession No. ML19032A609) is presented below.

RULEMAKING PLAN

Title

"Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Material"

Regulation

This proposed rulemaking would affect Appendix B to 10 CFR Part 30. As explained in the scoping discussion below, 10 CFR 30.35 and 10 CFR 70.25 may also be affected.

Regulatory Issue

The regulatory issue presented by the petition is whether to amend Appendix B to add unlisted isotopes and assign them specific possession values that better reflect the amount of financial assurance required for the isotopes possessed. For consistency, staff would reset values for

² Advanced Accelerator Applications commented that "[f]or any FDA approved [sic] radiopharmaceutical, with an associated radionuclidic [sic] contaminant, we believe 10 CFR 30.35 financial assurance and recordkeeping for decommissioning should not apply."

³ Comments of Nuclear Information and Resource Service, Food & Water Watch, and Toledo Coalition for Safe Energy, December 6, 2017. (ADAMS Accession No. ML17341A057).

⁴ According to several commenters, actinium-227, aluminum-26, silicon-32, sodium-22, thorium-228, and titanium-44 should all be listed because they have potential medical uses. Five commenters recommended listing lutetium-177m, a metastable byproduct of the medical isotope lutetium-177. One commenter noted that rhenium-184m should be listed because it is an activation product from certain cyclotron target windows used to produce other isotopes. Other commenters said that actinium-227, cobalt-57, and thorium-227 should be listed because the current restrictions on their possession could adversely affect the availability of other products. (ADAMS Accession No. ML18292A481).

listed isotopes using the same, more risk-informed method. In addition, Appendix B's title does not reflect its current use, and most of its listings are for isotopes with half-lives not subject to decommissioning funding requirements. Finally, because Appendix B's values were not derived using modern risk-informed methods, some licensees may be required to provide more decommissioning funding than warranted by the risks of decommissioning their facilities.

Existing Regulatory Framework

For byproduct material with a half-life greater than 120 days, NRC regulations at 10 CFR 30.35 and 70.25 require decommissioning financial assurance to possess a quantity greater than a calculated minimum based on Appendix B and the licensee's possession limit for that material. The tables in 10 CFR 30.35(d) and 10 CFR 70.25(d) require identically increasing amounts of funding for identically increasing quantities of the isotope possessed. For unsealed byproduct or special nuclear material (SNM), depending on the licensee's possession limit, paragraph (d) requires either \$225,000 or \$1,125,000.⁵ If the licensee's possession limit exceeds the paragraph (d) maximum of 100,000 times the applicable Appendix B value, paragraph (a) requires a decommissioning funding plan (DFP) with an amount based on the larger limit. Because DFPs are intended for facilities possessing these larger quantities, DFPs are generally costlier than the \$1,125,000 maximum prescribed under paragraph (d) for possession limits greater than 10,000 to 100,000 times the applicable Appendix B value.

For isotopes not explicitly listed in Appendix B, the default possession values significantly limit the quantity of an unlisted isotope a licensee may possess without decommissioning financial assurance.⁶ For an unsealed non-alpha-emitting isotope, for example, 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. To possess more than 1 mCi of the isotope would require \$1,125,000, and a DFP would be required to possess more than 10 mCi. Enclosure 1 discusses the historical origin of all Appendix B values.

For many facilities that use small quantities of unlisted isotopes, the expense of providing a DFP or one of the funding amounts in paragraph (d) may not be commensurate with the radiological risks of decommissioning. One example is the Ge-68 generator of Ga-68 for medical imaging, which typically must ship with at least 50 mCi to provide cost-effective imaging. In a 2015 report, the Advisory Committee on Medical Uses of Isotopes (ACMUI) found that "current Part 30 regulations are preventing and/or deterring the use of promising ... Ga-68 diagnostic imaging agents for patients due to the decommissioning funding plan burden for its parent Ge-68."⁷

⁵ For sealed sources or plated foils, 10 CFR 30.35(d) requires \$113,000 to possess a quantity greater than 10^{10} but not more than 10^{12} times the Appendix B value. To possess sealed sources or plated foils in a quantity greater than 10^{12} times the Appendix B value, 10 CFR 30.35(a)(2) requires a DFP.

⁶ 0.1 microcurie (μCi) for unsealed non-alpha-emitting nuclides, and 0.01 μCi for unsealed alpha-emitters.

⁷ Germanium-68/Gallium-68 Decommissioning Funding Plan Final Report and Addendum, August 12, 2015 (ADAMS Accession No. ML15231A047). After analysis, the staff agreed that the DFP requirement is not necessary for licensees using Ge-68 generators, and developed licensing guidance allowing an affected licensee to obtain an exemption from DFP requirements. See "Authorization for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators," July 29, 2016 (ADAMS Accession No. ML16082A415) and "Revision of Technical Basis for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators," July 13, 2017 (ADAMS Accession No. ML17075A487).

Explanation of Why Rulemaking is the Preferred Solution

The staff evaluated the following options other than rulemaking:

- Exemptions (No Action) – this option would continue the need for case-by-case reviews of exemption requests. It is not as efficient as other options and misses an opportunity to apply a more risk-informed methodology for setting decommissioning funding requirements and the amount of financial assurance required.
- Guidance – guidance documents have no legal authority to alter Appendix B's default possession thresholds. Licensees currently need exemptions from those thresholds, and guidance would, therefore, not resolve the issues raised by the petition.
- Enforcement Discretion or Orders – these mechanisms are not appropriate substitutes for rulemaking to address the issues raised by the petition, which are generic, not related to regulatory compliance, and do not raise concerns about adequate protection of public health and safety or the common defense and security.⁸

The staff recommends rulemaking because it would establish a more stable, risk-informed basis for decommissioning funding requirements by using isotope-specific possession values that better reflect the amount of financial assurance required. The rulemaking would thus be less costly in the long term to both the NRC and licensees than continuing to conduct exemption reviews for users of unlisted isotopes. A more detailed discussion on expected benefits is provided in the resources section below.

Description of Rulemaking: Scope

To better risk-inform Appendix B possession values, and to identify and incorporate opportunities for transformative change, the staff would seek public input on two potential rulemaking approaches:

- (1) developing a new methodology based on decommissioning risk factors; or
- (2) replacing the listings and values in Appendix B with those of Appendix C to Part 20, "Quantities of Licensed Material Requiring Labeling," for isotopes with a half-life greater than 120 days.

Under either option, the revised possession values may be smaller than those currently listed in Appendix B. Appendix C's possession values for seven isotopes, including SNM isotopes,⁹ are 10 times smaller than those in Appendix B, and a new risk-informed methodology could also result in smaller Appendix B values for some isotopes, although the staff does not expect it. If the method for setting new possession values were to result in smaller Appendix B values, the staff would consider ways to ensure that these values do not decrease current decommissioning funding thresholds. For example, the staff would consider increasing the multiplier values in 10

⁸ Using an Enforcement Guidance Memorandum (EGM) to exercise long-term enforcement discretion in lieu of rulemaking would be inconsistent with the Enforcement Manual, which specifies that EGMs are not to be used in place of rulemaking or exemption processes. Orders are issued when necessary either to ensure compliance with existing regulations or to provide adequate or enhanced protection of public health and safety or the common defense and security. Neither justification applies here.

⁹ The Appendix C value is 10 times smaller than the current Appendix B value for americium-241, cadmium-109, plutonium-239, uranium-233, -234, and -235, and zirconium-93.

CFR 30.35(d) and 10 CFR 70.25(a)(2) and (d) to compensate for the smaller new Appendix B possession values. The potential impacts of either option are discussed in the Cumulative Effects of Regulation (CER) section below.

The scope of this rulemaking may also include § 30.35(d) requirements for the physical form of a material. For a given Appendix B value, § 30.35(d) provides separate financial assurance requirements for sealed and unsealed material. Taking into account any comments received on the petition, the staff would examine the merits of creating a new category for isotope generators that provide an engineered confinement greater than an unsealed form but less than that of a sealed source.

Finally, the rulemaking would retitle Appendix B to clarify that its purpose is for calculating decommissioning funding requirements, not setting possession values for labeling. The rulemaking would also remove the Appendix's 130 listings of isotopes with a half-life of 120 days or less, since these isotopes are not subject to decommissioning financial assurance requirements.

Description of Rulemaking: Preliminary Backfitting and Issue Finality Analysis

Part 30 licensees are not within the scope of any backfitting or issue finality provisions,¹⁰ and the backfit rule in Part 70 applies only to Part 70 licensees using SNM isotopes in quantities greater than a critical mass, and Part 70 licensees engaged in activities the Commission determines could significantly affect public health and safety. The rulemaking is unlikely to result in a backfit to fuel cycle and other large industrial SNM licensees because the quantities they possess already require them to have a DFP. The rulemaking would only be a backfit if the method used to revise SNM possession values produced a value smaller than the existing Appendix B value, causing the licensee to be subject to new or additional decommissioning requirements. Although considered unlikely, if a backfit analysis is needed, the staff will prepare an analysis as required in 10 CFR 70.76 and in conformity with Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests."

Description of Rulemaking: Estimated Schedule

Initiate regulatory basis phase – after the Commission decision on the rulemaking plan.
Complete regulatory basis – 12 months after the Commission decision.
Submit proposed rule to the Commission – 12 months after completing the regulatory basis.
Submit final rule to the Commission – 12 months after the proposed rule.

All schedules include time to coordinate reviews with the Agreement States and the ACMUI. The staff will continue to look for opportunities to compress these schedules as the work proceeds.

¹⁰ Although Part 30 contains no backfit or issue finality provisions for byproduct material licensees, the staff will consider measures to compensate for the adverse effects of smaller new Appendix B possession values where such measures would not compromise adequate protection of public health and safety. As with any similarly-affected SNM licensees, one option could be to increase the corresponding multiplier values in Part 30(a)(2) and (d) by an order of magnitude sufficient to compensate for the smaller new Appendix B possession values.

Description of Rulemaking: Preliminary Recommendation on Priority

Based on the Common Prioritization of Rulemaking prioritization methodology (ADAMS Accession No. ML18263A070), the preliminary priority for this rulemaking activity is medium. It would be a moderate contributor to the safety goal in the NRC's FY 2018-2022 Strategic Plan (ADAMS Accession No. ML18032A561) by supporting Strategies 2 and 3 (Factor A in the prioritization methodology). The rulemaking would also advance the Plan's Efficiency, Clarity, and Reliability Principles of Good Regulation (Factor B), close a regulatory gap caused by default Appendix B values that are insufficiently risk-informed (Factor C), and both reduce regulatory burden and respond to a petition for rulemaking (Factor D).

The priority for a rulemaking activity can change over time. Common reasons for a change in priority are new Commission or senior management direction or changes in the rulemaking's scope as it goes through the rulemaking process.

Description of Rulemaking: Estimate of Resources

The proposed action is estimated to involve a medium to high magnitude of costs, depending on the need to develop a new risk-informed methodology for setting Appendix B possession values (approach 1). For either rulemaking approach, there would be a need for interaction with Agreement States, ACMUI, and other stakeholders. A more detailed breakdown of estimated resources is provided in Enclosure 2, "Rulemaking Resource Estimate."

The proposed action is expected to provide the following benefits:

- More Risk-Informed Calculation of Decommissioning Funding Costs – would use isotope-specific possession values that better reflect expected decommissioning costs.
- Enhancement of Regulatory Framework for NARM – would add NARM isotopes and possession values to Appendix B.
- More Cost Effective than Continued Exemption Reviews – the total number of exemption requests likely to be filed in the absence of a rulemaking is unknown, but their aggregated costs over time would likely exceed those of a one-time rulemaking.¹¹
- Stronger Regulatory Framework for New Technologies – the staff anticipates that this rulemaking would also make new medical and industrial technologies available to the general public faster and at lower cost without compromising safety. Although a precise estimate of the value of these benefits is unknown, the staff anticipates that they are likely to be both quantitative, in the form of the wider availability of new technologies, and qualitative, in the form of, for example, better resolution in radiodiagnostic imaging.

¹¹ The current generic bounding estimate for the cost of a license exemption is \$278,000, consisting of an estimated \$188,000 for the licensee's development and submittal of a license amendment request, and an estimated \$90,000 for NRC's review. As of July 2019, NRC staff had processed 7 DFP exemption requests for Ge-68 generators, and there are 22 licensees authorized to possess Ge-68. Some of these other Ge-68 licensees may also want exemptions from the DFP requirement, and other applicants may seek exemption requests for other unlisted isotopes.

Cumulative Effects of Regulation

For licensees using unlisted isotopes, this proposed rulemaking would effectively remove the applicability of Appendix B's default possession thresholds without the time and expense of case-by-case exemption reviews. Such a generic action would thus reduce the cumulative regulatory burden on these licensees.

For licensees using listed isotopes, the cumulative effects may vary by isotope. If the method for setting Appendix B possession values produced a new value smaller than the current one for a given isotope, and if an affected licensee could not reduce its possession limit enough to compensate for the smaller value, the licensee could become subject to new or additional financial assurance requirements. However, the staff anticipates that, in general, a methodology accounting for expected decommissioning risks would result in the same or larger values for most isotopes. In addition, as described above, the staff will consider options to ensure that decommissioning funding requirements are not unjustifiably increased even if smaller values result.

Because the decommissioning financial assurance requirements of § 70.25 are tied to Appendix B to Part 30, a revision of Appendix B's possession values could adversely affect some licensees possessing SNM. However, since most such licensees possess these isotopes in quantities large enough to require a DFP, the impact, if any, is expected to be minimal.

The CER impacts of this proposed rulemaking could affect Agreement States, which are required to adopt compatible regulations within 3 years after promulgation of an NRC rule requiring compatibility. No Agreement State commenting on the petition raised CER issues.

The staff will request comments on the draft regulatory basis document, proposed and final rule, and draft guidance document(s) to identify potential CER impacts.

Agreement State Considerations

The staff would invite an Agreement State representative to participate in the development of the regulatory basis document, the proposed and final rules, and any accompanying guidance documents. Because Agreement State agencies must adopt compatible State regulations, the staff would also consult Agreement State representatives if any changes in Compatibility Category designations for § 30.35 requirements are necessary.

Guidance

The staff expects that NUREG-1757, Volume 3, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," will need to be updated in parallel with the rulemaking. Portions of the NUREG are likely to need revisions to incorporate the results of any method used to set new Appendix B possession values, especially if it depends on identifying the specific risks of decommissioning facilities.

Advisory Committee on Reactor Safeguards (ACRS) Review

The staff expects that the proposed changes would affect users at medical and academic facilities, but if the staff were to identify any potential impacts on SNM facility licensees, the staff would promptly engage the ACRS to evaluate those impacts.

Committee to Review Generic Requirements (CRGR) Review

The staff recommends that CRGR review the recommended rulemaking to identify and evaluate any potential backfits affecting SNM licensees during the development of the regulatory basis or proposed rule.

Advisory Committee on the Medical Use of Isotopes Review

The staff recommends that the ACMUI review this rulemaking because it would affect the use of medical isotopes. The staff would coordinate with the ACMUI during the development of the regulatory basis document, the proposed and final rule, and any accompanying guidance. The staff has adjusted the rulemaking schedule to reflect this coordination.

Analysis of Legal Matters

The Office of the General Counsel has reviewed this rulemaking plan and has not identified any issues necessitating a separate legal analysis at this time.

COMMITMENT:

If the Commission approves this rulemaking plan, the staff would proceed in accordance with SECY-16-0042, "Recommended Improvements for Rulemaking Tracking and Reporting," dated April 4, 2016 (ADAMS Accession No. ML16075A070). The staff would update an inactive entry in the agency's rulemaking tracking tool to replace a previously planned rulemaking to relieve Ge-68 generator licensees from the DFP requirement. The existing docket number, NRC-2017-0031, would be used, and it would be retitled, "Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Material," to reflect the broader scope. The staff would budget for this rulemaking during the next budget formulation cycle.

RECOMMENDATION:

The NRC staff recommends that the Commission:

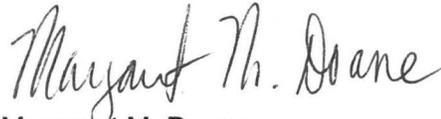
1. Approve initiation of a rulemaking to close PRM-30-66 based on the plan described in this paper and the resource estimate set forth in Enclosure 2;
2. Approve publication of a *Federal Register* notice announcing and explaining its determination on PRM-30-66 (Enclosure 3); and
3. Note that:
 - a. The appropriate Congressional committees will be informed,
 - b. A letter is enclosed for the Secretary's signature (Enclosure 4) informing the petitioner of the Commission's decision on the petition, and
 - c. The Office of Public Affairs does not plan to issue a press release.

RESOURCES:

Enclosure 2 includes an estimate of the resources needed to complete this rulemaking.

COORDINATION:

The Office of the General Counsel has no legal objection to this action. The Office of the Chief Financial Officer has reviewed this paper and has no concerns with the estimated resources in the enclosure.



Margaret M. Doane
Executive Director
for Operations

Enclosures:

1. Background on Origin of Appendix B Possession Values
2. Rulemaking Resource Estimate
3. *Federal Register* Notice
4. Letter to Petitioner

SUBJECT: PETITION FOR RULEMAKING AND RULEMAKING PLAN ON
 DECOMMISSIONING FINANCIAL ASSURANCE REQUIREMENTS FOR SEALED AND
 UNSEALED BYPRODUCT MATERIAL

ADAMS Accession No: ML18292A434

*Concurred by e-mail

OFFICE	NMSS/REFS	NMSS/REFS	NMSS/REFS	NMSS/REFS	NMSS/REFS
NAME	RMacDougall*	ALoveBlair*	JShepherd*	CBladey*	JCai*
DATE	5/16/19	3/29/19	11/5/19	6/7/19	9/25/19
OFFICE	NMSS/REFS	NMSS/DUWP	NMSS/MSST	RIII/DNMS	OGC
NAME	CCarusone (for JTappert)*	PHolahan*	AKock*	CLipa (for DPelton)*	LSClark*
DATE	9/30/19	10/2/19	10/2/19	10/3/19	11/12/19
OFFICE	OCFO	NMSS/TE	NMSS	EDO	
NAME	MSampson*	LMoorin	JLubirski	MDoane 	
DATE	10/30/19	11/20/19	11/26/19	12/1/19	

OFFICIAL RECORD COPY