[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 30

[Docket No. PRM-30-66; NRC-2017-0159; NRC-2017-0031]

Naturally-Occurring and Accelerator-Produced Radioactive Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; consideration in the rulemaking process.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will consider in its rulemaking process issues raised in a petition for rulemaking submitted by Matthew McKinley on behalf of the Organization of Agreement States (OAS, the petitioner)[1]. The petitioner requests that the NRC amend its decommissioning financial assurance regulations for sealed and unsealed byproduct material not listed in a table that sets out ~~radioisotope~~radionuclide possession values for calculating these financial assurance requirements. The NRC will also examine ways to make the table's values and other NRC decommissioning funding requirements more risk-informed.

DATES: The docket for the petition for rulemaking, PRM-30-66, is closed on [**INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER***].

ADDRESSES: Please refer to Docket ID NRC-2017-0031 when contacting the NRC

1 Under the Atomic Energy Act of 1954, as amended, States with qualifying regulatory programs compatible with the NRC's may enter into binding agreements with the NRC to regulate materials not used in a nuclear power or research reactor. These States, called Agreement States, regulate most of the industrial and medical uses of radioactive materials in the United States, and the OAS is their national organization.

about the availability of information related to the future rulemaking~~Further NRC action on the issues raised by this petition can be found on the Federal rulemaking Web site at https://www.regulations.gov by searching on Docket ID NRC-2017-0031, the docket identification number for the future rulemaking~~.

~~—~~Please refer to Docket ID NRC-2017-0159 when contacting the NRC about the availability of information for this petition closure. You may obtain publicly-available information related to this action by any of the following methods:

Commented [A1]: Join with previous paragraph

- **Federal Rulemaking Web Site:** Public comments and supporting materials related to this petition can be found at https://www.regulations.gov by searching on the petition Docket ID NRC-2017-0159. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **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 e-mail to pdr.resource@nrc.gov. For the reader's convenience, instructions about obtaining materials referenced in this document are provided in Section VI, "Availability of Documents."

- **NRC's Public Document Room (PDR):** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Robert MacDougall, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-5175, e-mail: Robert.MacDougall@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Summary of the Petition

The NRC received a petition for rulemaking dated April 14, 2017, filed by Matthew McKinley on behalf of the Organization of Agreement States. ~~(OAS, the petitioner).~~[2] On August 23, 2017, the NRC published a notice of docketing and request for comment on the petition (82 FR 39971).

The petitioner requests that the NRC amend its existing regulations in appendix B, "Quantities of Licensed Material Requiring Labeling," in part 30 of title 10 of the *Code of Federal Regulations*, "Rules of General Applicability to Domestic Licensing of Byproduct Material," to ~~specifically~~ add appropriate unlisted ~~radioisotope~~radionuclides and their corresponding ~~activity possession~~ values. ~~The requirements in part 30's §~~ Section 30.35, "Financial Assurance and Recordkeeping for Decommissioning," uses multiples of the applicable quantities of material listed~~refer to the list~~ in appendix B to

~~2 Under the Atomic Energy Act of 1954, as amended, States with qualifying regulatory programs compatible with the NRC's may enter into binding agreements with the NRC to regulate materials not used in a nuclear power or research reactor. These States, called Agreement States, regulate most of the industrial and medical uses of radioactive materials in the United States, and the OAS is their national organization.~~

determine the~~enable licensees to determine their~~ need for decommissioning financial assurance for sealed and unsealed radioactive materials. Licensees using ~~isotope~~radionuclides not specifically listed in this appendix must use generic default values that the petitioner believes result in overly burdensome requirements.

Without this rulemaking, the petitioner asserts, "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 special exemptions.… Rather than issuing exemptions on a case by case basis, the more appropriate way to address the inconsistency in Appendix B['s treatment of listed and unlisted ~~isotope~~radionuclides] is to amend it to add appropriate nuclides and their corresponding activities, as determined by a rulemaking working group."

The petitioner also notes that the NRC did not update appendix B when the Energy Policy Act of 2005 amended the Atomic Energy Act of 1954 to give the NRC regulatory authority over discrete sources of naturally-occurring and accelerator-produced radioactive material~~s~~ (NARM). A significant number of medical ~~isotope~~radionuclides are accelerator-produced. Although the NRC did update schedule B of part 30, which lists possession values of byproduct material exempt from the requirements for a license, to add some NARM ~~isotopes and possession values for exemption purposes~~, it did not do the same for appendix B, the petitioner points out, even though appendix B is "the driver" for decommissioning financial assurance.

The petition is available in ADAMS under Accession No. ML17173A063.

II. Background

To determine the amount of decommissioning financial assurance required to possess a given ~~isotope~~radionuclide with a half-life greater than 120 days, a licensee must multiply the appendix B value for that ~~isotope~~radionuclide by the applicable number~~order of magnitude~~ in §§ 30.35 or 70.25. Sections 30.35(a) and 70.25(a) require a license-specific decommissioning funding plan (DFP) to possess a quantity of radionuclides greater than provided in the corresponding tables set forth in §§ 30.35(d) and 70.25(d). These tables require specific amounts of funding for specified ranges in the quantity of the ~~isotope~~radionuclide possessed. Both tables' funding amounts and quantity ranges are identical, but § 30.35 applies to byproduct material ~~isotopes~~ and § 70.25 applies to special nuclear material ~~isotopes~~.[3] Although the petition addressed only byproduct material licensed under part 30, appendix B has an identical use for special nuclear material licensed under part 70.

Section 30.35 sets a series of thresholds for decommissioning funding for possession and use of byproduct material. If the license authorizes possession of an unsealed ~~isotope~~radionuclide in a quantity more than 1,000 times its appendix B value, the licensee must provide $225,000 in financial assurance for decommissioning. If authorized to possess more than 10,000 times the appendix B value of that ~~isotope~~radionuclide, the licensee must provide $1,125,000. To possess more than 100,000 times the appendix B value, the licensee must provide a DFP for~~that requires~~ an amount based on the license's possession limit for the ~~subject isotope~~radionuclide. For ~~isotope~~radionuclides in the form of plated foils or sealed sources, a licensee must

3 Similar to § 30.35, § 70.25 includes a table that establishes decommissioning funding amounts based on the quantity of special nuclear material a licensee is authorized to possess. ~~Subject to additional provisions for combinations of isotopes, § 70.25(d) requires financial assurance for decommissioning in the amount of $225,000 if the license authorizes possession of an isotope in a quantity more than 1,000 times its appendix B value, and the licensee must provide decommissioning financial assurance in the amount of $1,125,000 if the license authorizes possession of more than 10,000 times the appendix B value of an isotope. When a license authorizes possession limits that exceed those quantities, the licensee must base financial assurance on a DFP.~~

provide $113,000 in financial assurance for decommissioning to possess more than 10 billion times the appendix B value for the ~~isotope~~radionuclide, and a DFP to possess more than a trillion times the appendix B value.

Appendix B also includes possession values for ~~isotope~~radionuclides not specifically listed. Known as the "default" possession values, these are equal to the lowest values listed in Appendix B for specific alpha-emitting and non-alpha-emitting radionuclides, respectively~~quite small~~, and ~~significantly~~ restrict the quantity a licensee may possess without having to meet the applicable~~one of these~~ financial assurance requirements. For unlisted ~~isotope~~radionuclides that are in unsealed form and do not emit alpha radiation, the default possession value is 0.1 microc~~C~~uries (µCi, one~~a~~ millionth of a c~~C~~urie), and for unsealed unlisted alpha-emitters, the default value is 0.01 µCi. Thus, using the table in § 30.35(d), a licensee would need to~~must~~ provide financial assurance for decommissioning funding of $225,000 to possess more than 0.1 millicurie (mCi, one~~a~~ thousandth of a c~~C~~urie) of an unsealed non-alpha-emitting ~~isotope~~radionuclide not listed in appendix B. To possess more than 1 mCi of such a~~n~~ ~~isotope~~radionuclide, the licensee ~~must~~ would need to have financial assurance for decommissioning of $1,125,000. A DFP is required to possess more than 10 mCi. For unsealed alpha-emitting ~~isotope~~radionuclides not listed in appendix B, the corresponding threshold quantities are 0.01 mCi ~~to trigger the need~~ for $225,000 in financial assurance, 0.1 mCi for~~to trigger the~~ $1,125,000 ~~requirement~~, and 1 mCi for a~~to trigger the~~ DFP ~~requirement~~.

These default values for unlisted ~~isotope~~radionuclides did not originate with a decommissioning funding purpose in mind. The default~~s~~ values, like the other values now in appendix B, were originally established to conform possession thresholds for the labeling of radioactive materials with the thresholds requiring a license, so that a label

would only be required to possess an isotope in a quantity that required a license. The labeling values, issued in 1970 in appendix C to part 20 (35 FR 6425; April 22, 1970), were redesignated in 1993 for decommissioning funding purposes as appendix B to part 30 (58 FR 67659; December 22, 1993).

~~Nor were a~~Appendix B~~'s labeling-derived~~ values were not based on an explicit consideration of risk, which ~~must~~ involves an evaluation of the probability as well as the consequence of a postulated event. ~~They~~ Appendix B values were based on a deterministic approach to regulation, which was widely used to develop early radiation protection requirements (60 FR 42622; August 16, 1995). Under this deterministic approach, the function of a safety limit is to ensure that the consequences of a postulated credible event would be acceptably small. Although the determination that an event is credible involves some consideration of probability~~risk~~, safety limits set deterministically are, by definition, not considered~~fully~~ risk-informed, because the probability of the event is not required to be fully considered. Despite their derivation from values established deterministically for labeling purposes, however, the NRC's experience with appendix B's possession values over more than 30 years has shown that they are generally adequate to determine the level of funding assurance required for decommissioning~~ly address the risk that a licensee might not have sufficient funding for decommissioning~~.

The DFP requirements in § 30.35(e) were also established with a different purpose in mind. Originally set forth in the 1988 decommissioning rule (53 FR 24018, 24035, 24043; June 27, 1988~~, see pp. 24035, 24043~~), DFPs were intended for major facilities possessing large quantities of radioactive material, not for facilities possessing the ~~relatively small~~ quantities of ~~isotope~~radionuclides typically used by medical licensees. Licensees of these major~~larger~~ facilities are required to submit a DFP with a

cost estimate specific to their facilities. Although ~~smaller~~ medical and industrial licensees possessing smaller quantities of radioactive material may also develop facility-specific decommissioning cost estimates, it is not necessary to ensure adequate decommissioning funding, and not cost effective for many such licensees. When the rule was issued, it was estimated that very few such licensees possessing such smaller quantities would need DFPs.

These DFPs are subject to detailed requirements for their original content and ongoing maintenance. Under~~In accordance with~~ § 30.35(e), DFPs~~they~~ must contain, among other things, a detailed cost estimate for an independent contractor to decommission the site for release for unrestricted use, and a certification that financial assurance in the amount of the cost estimate has been provided. The licensee must resubmit the DFP every 3 years with adjustments as necessary to account for changes in costs and the extent of contamination. Even if a licensee possesses only one ~~radioisotope~~radionuclide in a quantity requiring a DFP, that DFP must also cover all other ~~radioisotope~~radionuclides at the site, whether or not~~even if~~ the aggregated total quantity of these other ~~isotope~~radionuclides would ~~not otherwise~~ have required a ~~triggered the~~ DFP ~~requirement~~.

The NRC staff has determined that DFPs are not likely to be necessary for licensees that possess small quantities of certain ~~an~~ unlisted ~~radioisotope~~radionuclides, particularly if it is returned in its container to the manufacturer/distributor (M&D) after use. This has been the case for germanium-68 (Ge-68) generators of the medical ~~isotope~~radionuclide gallium-68 (Ga-68).

In an August 2015 report on the effect of the DFP requirement on Ge-68 generators, the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) concluded 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" (ADAMS Accession No. ML15231A047).

After analysis, the NRC staff agreed that the DFP requirement could impede or limit patient access to the radiopharmaceuticals developed from these generators and that a DFP is not necessary to ensure the safe decommissioning of facilities that use them. Pending rulemaking, the NRC staff developed guidance on the issuance of exemptions from the DFP requirement for licensees that have entered into written agreements binding them to return the generators to an M&D and binding the affected M&D to accept them.

~~The guidance allows exemptions only from the DFP requirement, however, and only for licensees using Ge-68 generators. The guidance is a temporary measure; if the NRC determines not to issue a rule addressing decommissioning funding requirements for such licensees, the guidance will be retracted and consideration of exemption requests will revert to case-by-case reviews.~~

Beyond the impact on Ge-68 generator licensees, a decision to forego rulemaking would also be likely to elicit requests for exemptions from existing decommissioning funding requirements by users of other unlisted ~~isotope~~radionuclides. As noted in Section IV. below, commenters have identified several ~~isotope~~radionuclides with actual or potential medical applications that are or could be negatively affected because these ~~isotope~~radionuclides are not currently listed in appendix B.

III. Discussion

The petitioner advances three main reasons for amending appendix B to part 30. First~~One is that~~, although Congress gave the NRC regulatory authority over discrete

sources of NARM in 2005, the NRC has not updated appendix B to add possession values for any NARM ~~isotopes~~, which accounts for an increasing number of medical uses.

Second, t~~T~~he petitioner~~'s~~ argues~~second reason for rulemaking arises from its argument~~ that the default possession values for ~~isotope~~radionuclides not listed in appendix B force regulators either to "apply overly burdensome financial assurance obligations" or "evaluate case by case special exemptions."

The petitioner's third reason~~argument~~ for rulemaking cites the time and cost impacts of needing to request and process exemptions from these requirements on a case-by-case basis. 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~~radionuclides 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."

IV. Public Comments on the Petition

Overview of Public Comments

The original comment period on PRM-30-66 closed on November 6, 2017. To allow a larger number of stakeholders to comment, the NRC published a *Federal Register* notice extending the comment period to December 6, 2017. The NRC received 20 comment submissions containing 137 discrete comments. Comments came from industry, government and non-government organizations, and members of the public. The name of the commenter, the commenter's affiliation (if any), and the ADAMS

accession number for each comment submission are provided in the following table, listed alphabetically by affiliation.

Commenter	Affiliation	ADAMS Accession Number
Bill Diamantopoulos	Advanced Accelerator Applications	ML17307A292
David Walter	Alabama Office of Radiation Control	ML17276A099
Melissa Martin	American Association of Physicists in Medicine	ML17321A166
James Brink	American College of Radiology	ML17321A167
Michael Baxter	American Pharmacists Association	ML17307A461
Anonymous	Anonymous	ML17345A861
Angela Minden	Arkansas Department of Health Radiation Control Section	ML17311A614
Glenn Sullivan	Cardinal Health	ML17311A618
Conference of Radiation Control Program Directors' Committee on Nuclear Medicine	Conference of Radiation Control Program Directors	ML17345A862
Michael Guastella	Council for Radionuclides and Radiopharmaceuticals	ML17311A616
Kimberly Steves	Kansas Department of Health and Environment	ML17325B724
Glenn Sturchio	Mayo Clinic	ML17338A830
B. J. Smith	Mississippi Department of Health	ML17279B157
Catherine Ribaudo	National Institutes of Health	ML17311A612
Diane D'Arrigo, Hugh MacMillan, and Terry Lodge	Nuclear Information and Resource Service, Food & Water Watch, and the Toledo Coalition for Safe Energy	ML17341A057
Hendrik Engelbrecht and Richard Van Sant	PharmaLogic Holdings Corp. and subsidiaries	ML17345A859
Susan Langhorst	Private Citizen	ML17311A619
Caitlin Kubler and Bennett Greenspan	Society of Nuclear Medicine and Molecular Imaging	ML17321A165
Roger Macklin	Tennessee Department of	ML17296A183

	Environment and Conservation	
Lt. Col. Scott Nemmers	U.S. Air Force, Master Materials License Management Staff	ML17312B336

In its *Federal Register* notice announcing the docketing of the petition, the NRC posed four questions related to the petition's~~its~~ scope. The NRC analyzed the comments received in response, sorted them into 47 categories of common concerns, and traced each category to one of the questions in the notice (See "Categorization of Comments on NRC Questions about PRM-30-66" (ADAMS Accession No. ML18292A481.)) Below are summaries of the principal categories of comments received in response to each of the questions. The NRC evaluated each comment in deciding whether to consider or deny the issues raised by the petitioner. The NRC will also consider the comments further during the development of the regulatory basis document for this rulemaking and any methodology for setting more risk-informed appendix B values. These documents will be made available for public comment.

Summaries of Responses to the NRC's Questions

Question 1: What products or technologies, other than the Ge-68 generators cited in the petition, are being or could be negatively affected because the radioactive materials required for these products or technologies are not currently listed on the table in appendix B?

Most of the commenters who responded to this question stated that LUTATHERA® (lutetium-177 oxodotreotide), a radiopharmaceutical used to treat gastro-entero-pancreatic neuro-endocrine tumors, could be negatively affected because a contaminant in this radiopharmaceutical, a metastable isomer~~tope~~ of lutetium-177 (Lu-177m), is not listed in appendix B to part 30.

Commenters also identified several other radionuclides whose use could be unnecessarily restricted because they are not listed in appendix B. Actinium-227, thorium-228, and titanium-44 are being considered for potential radionuclide generators, commenters stated. Silicon-32 has potential therapeutic applications, and sodium-22 and aluminum-26 have potential diagnostic applications. One commenter noted that rhenium-184m should be listed because it is an activation product from certain cyclotron target windows used to produce other ~~isotope~~radionuclide~~s~~. Other commenters identified cobalt-57 because the use of products based on or associated with it could be negatively affected.

Question 2: Please provide specific examples of how the current NRC regulatory framework for decommissioning financial assurance has put an undue hardship on potential license applicants. Explain how this hardship has discouraged the development of beneficial new products, or otherwise imposed unnecessarily burdensome requirements on licensees or members of the public (e.g., users of medical diagnostic or therapeutic technologies) that depend on NARM.

Commenters provided several examples of undue hardship. Commenters said that t~~T~~he DFP requirement is a hardship for medical licensees with multiple locations of use~~, commenters said~~, since a DFP is required for each site using an unlisted ~~radioisotope~~radionuclide. Commenters also noted that the need to seek case-by-case exemptions from appendix B's default requirements is an administrative burden, and that the regulatory delays in obtaining exemptions from the financial assurance hardships negatively affect patient care.

Three commenters also said that the NRC should address inequities in applying § 30.35 in different States. One commenter said that the increased financial assurance burden for those possessing accelerator-produced ~~isotope~~radionuclide~~s~~ "cascades to

the Agreement States, which look to NRC for guidance, and absent that guidance they either move forward on their own or temporarily stop processing [license] amendment requests [for exemptions]."

Question 3: Given the NRC's current regulatory authority over the radiological safety and security of NARM, what factors should the NRC take into account in establishing possession limits for any of these materials that should be listed in appendix B?

Thirteen commenters provided a total of 38 recommendations on factors the NRC should consider in setting any new possession limits. Several of these recommendations shared common themes. One was that the NRC should provide special regulatory consideration for~~consider that~~ radiopharmaceuticals~~ deserve special regulatory consideration~~. Four commenters said, for example, that the NRC should consider the unique purpose of radiopharmaceuticals, the importance of patient access to these pharmaceuticals, and the fact that they undergo extensive evaluation by the U.S. Food and Drug Administration before they are allowed to be manufactured and regulated for their radiological properties.

A related theme was that generators using unlisted ~~isotope~~radionuclides to produce these radiopharmaceuticals also deserve special consideration. Five commenters said these generators should either be considered as sealed sources or as a separate category qualifying for more risk-informed regulatory treatment.

Another theme was that for appendix B to part 30, the NRC should consider possession values already established in other NRC tables. Five commenters said, for example, that the NRC should align the values in appendix B to part 30 with those for the same ~~isotope~~radionuclides in appendix C to part 20 on labeling.

~~On other factors to take into account in setting new appendix B possession values, t~~Two commenters recommended similar sets of considerations with respect to which other factors should be accounted for in setting new appendix B possession values. These included the physical and chemical form and half-life of the ~~isotope~~radionuclide and its progeny, and the disposal pathway for these ~~isotope~~radionuclides at the time of facility decommissioning.

~~Most of the comments received in response to this question were about more specific factors that did not share a common theme.~~ Two commenters stated that in determining the amount of financial assurance required for a DFP, only the area of use of the subject radionuclide should be considered. These commenters noted that medical licensees use different ~~radioisotope~~radionuclides in different areas of their facilities, and that some of these ~~isotope~~radionuclides, such as technetium-99 and iodine-125, do not require any financial assurance for decommissioning.

Four other commenters shared a concern that establishing new possession limits in appendix B to part 30 could result in unsafe waste disposal practices. Three commenters submitting a single set of comments argued that possession values high enough to make decommissioning financial assurance requirements more commensurate with the radiological hazards of medical uses could also effectively exempt some industrial and commercial licensees, including those engaged in oil and gas fracking, from a requirement to dispose of their wastes in licensed facilities. These commenters also said that the NRC must prepare a "programmatic" (i.e., generic) environmental impact statement for any rulemaking to amend appendix B.

Two commenters raised issues about the number of ~~radioisotope~~radionuclides with half-lives greater than 120 days — the minimum, as noted at § 30.35, for decommissioning funding requirements — that should be added to appendix B. One

commenter said that the appendix should list all ~~isotope~~radionuclides with such half-lives, “since it is hard to predict where the next medically useful radionuclide will come from in the future.” The other commenter noted that appendix B to part 30 contains only 45 ~~isotope~~radionuclides (the staff counted 49) with half-lives greater than 120 days, while appendix C to part 20 lists 150.

One commenter on Question 3 suggested that, because the factors that need to be considered in setting new appendix B possession limits may change with time, the NRC should review part 30 decommissioning funding requirements every 3 to 5 years.

Question 4: Does this petition raise other issues not addressed by the questions above about labeling or decommissioning financial assurance for radioactive materials? Must these issues be addressed by a rulemaking, or are there other regulatory solutions that NRC should consider?

On the question of whether the NRC should consider solutions other than rulemaking, 15 of the 20 comment submissions explicitly supported the need for rulemaking, and one requested that § 30.35 requirements not apply to certain radiopharmaceuticals approved by the U.S. Food and Drug Administration—a change that can only be effected by rule. No commenters opposed rulemaking, although ~~the~~ three commenters that submitted a single set of comments were concerned that setting new possession limits for medical ~~isotope~~radionuclides could effectively exempt from needed regulation industrial wastes containing those ~~isotope~~radionuclides. Of those commenters that explicitly supported rulemaking, seven also said it would be preferable to issuing exemptions, and two said that a rulemaking would improve or minimize negative impacts on research, medical licensees, and the availability of new radiopharmaceuticals to patients.

On the question of whether the petition raised any issues not addressed by the other three NRC questions, responding commenters raised 16 additional issues. The majority of these are related to Question 3 on factors to be considered in setting new appendix B possession limits. Six commenters, for example, called on the NRC to address the inconsistencies in possession values between appendix B to part 30 and appendix C to part 20. Two of these commenters recommended replacing appendix B values with appendix C values, and one recommended that the NRC withdraw appendix B and reference appendix C instead.

Two other commenters recommended that the NRC describe the methodology for deriving possession values in a footnote to appendix B to part 30. Providing a formula instead of the current default values for unlisted ~~isotope~~radionuclides, one commenter said, "will alleviate the need for subsequent amendments to appendix B and minimize [the] negative impact (or potential impact) on medical licensees and patient care."

Four commenters raised a new issue unrelated to the issues associated with setting possession limits~~, however~~. These commenters noted that the title of appendix B to part 30, "Quantities of Licensed Material Requiring Labeling," does not express the actual purpose of the appendix.

V. Reasons for Consideration

The NRC has reviewed the petition in accordance with § 2.803(h). For several~~the~~ reasons ~~set out in this document~~, the NRC concludes that the issues raised by the petitioner and commenters should be considered in the rulemaking process. First, ~~One reason is that~~ the Energy Policy Act of 2005 gave the NRC regulatory authority over discrete sources of NARM, and the NRC needs to incorporate appropriate

NARM ~~isotopes~~ into its regulatory framework for decommissioning funding. This would also provide a clearer, more predictable basis for Agreement State regulation of decommissioning funding for these ~~isotope~~radionuclides. Second, r~~R~~ulemaking would also reduce, if not eliminate, the need to process exemption requests from licensees seeking a more risk-informed alternative to the generic default values that result in decommissioning funding requirements that are not commensurate with likely costs.

Moreover, ~~continuing to regulate the affected licensees indefinitely with case-by-case reviews of exemption requests is inconsistent with the NRC's principles of good regulation. A~~ a rulemaking would also advance the NRC's commitment to more risk-informed regulation by better aligning NRC funding requirements with the risks of decommissioning the affected licensee facilities.

In addition, the NRC expects that rulemaking would be more cost-effective~~efficient~~ than maintaining applicable existing regulations~~, for several reasons~~. ~~First, t~~The short-term savings to the NRC from denying this petition for rulemaking would likely be outweighed by the higher aggregate cost to license applicants, Agreement States, and the NRC for case-by-case exemption reviews over the long term. The higher cost of NRC inaction would accrue not only for Ge-68 generators and the Lu-177 radiopharmaceuticals cited by most commenters on Question 1, but foreseeably for other new technologies. In addition to making costly exemption reviews unnecessary, a rulemaking would also provide a more stable, risk-informed basis for decommissioning funding requirements by using ~~isotope~~radionuclide-specific possession values that better reflect the amount of financial assurance required.

Further, more predictable and risk-informed decommissioning funding requirements could remove an unnecessary barrier to making~~e~~ Ge-68 generator-supported Ga-68 imaging, Lu-177 radiotherapy, and other emerging medical and

industrial technologies that depend on unlisted ~~isotope~~radionuclides ~~more~~ available to the public ~~sooner, and at lower cost, without compromising safety~~.

An additional reason to undertake rulemaking on appendix B is to align its title with its decommissioning funding purpose.

Lastly, adding unlisted ~~isotope~~radionuclides in a single comprehensive rulemaking would minimize the need for additional rulemakings in the future when new applications are developed for ~~radioisotope~~radionuclides remaining unlisted in appendix B. ~~Conducting one rulemaking at the outset would fulfill the NRC's efficiency principle of good regulation, which calls for adopting the regulatory alternative that minimizes the use of resources.~~

VI. Availability of Documents

The documents identified in the following table, listed by their order of reference in this notice, are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession Number or *Federal Register* Citation
Petition letter of Organization of Agreement States Board Chairman Mathew McKinley, April 14, 2017	ML17173A063
Federal Register notice of docketing of petition for rulemaking PRM-30-66 and request for public comment, August 23, 2017	82 FR 39971
Federal Register notice extending comment period, November 6, 2017	82 FR 51363
Federal Register notice, Final rule, Part 20 - Standards for Protection Against Radiation, Appendix C, April 16, 1970	35 FR 6425

Federal Register notice, Final decommissioning rule, June 27, 1988	53 FR 24018
Federal Register notice, Final rule, removal of expired material, December 22, 1993	58 FR 67659
"Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement," August 16, 1995	60 FR 42622
"Categorization of Comments on NRC Questions about PRM-30-66"	ML18292A481
"Advisory Committee on the Medical Use of Isotopes Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) Final Report," August 12, 2015	ML15231A047
~~"Authorization for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators," July 29, 2016~~	~~ML16082A415~~
NRC Strategic Plan, Fiscal Years 2018-2022	ML18032A561

VII. Conclusion

For the reasons cited in this document, the NRC will consider in the rulemaking process the issues raised in PRM-30-66 and will seek public input on any proposed changes to its requirements in appendix B to part 30, 10 CFR 30.35, and 10 CFR 70.25. The rulemaking is titled "Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Materials." Publication of this notice in the *Federal Register* closes Docket ID NRC-2017-0159 for PRM-30-66.

The public can monitor further action on the rulemaking that will address this petition by searching Docket ID NRC-2017-0031 on the Federal rulemaking Web site,

https://www.regulations.gov. The site allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) search for and open the docket folder (NRC-2017-0031); (2) click the "E-mail Alert" link; and (3) enter an e-mail address and select the frequency for e-mail receipts (daily, weekly, or monthly). The NRC also tracks the status of all NRC rules and PRMs on its Web site at https://www.nrc.gov/about-nrc/regulatory/rulemaking/rules-petitions.html.

Dated at Rockville, Maryland, this xxth day of Xxxxx, 20XX.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.