

POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette L. Vietti-Cook, Secretary
FROM: Commissioner Baran
SUBJECT: SECY-19-0125: Petition for Rulemaking and Rulemaking Plan on Decommissioning Financial Assurance for Sealed and Unsealed Radioactive Material (PRM-30-66; NRC-2017-0159)

Approved Disapproved Abstain Not Participating

COMMENTS: Below Attached None

Entered in STARS

Yes

No



SIGNATURE

3/11/20

DATE

**Commissioner Baran's Comments on SECY-19-0125,
"Petition for Rulemaking and Rulemaking Plan on Decommissioning Financial Assurance
Requirements for Sealed and Unsealed Radioactive Material"**

I agree with the NRC staff that the agency should grant the Organization of Agreement States' petition for rulemaking to update Appendix B of Part 30. Adding unlisted isotopes to Appendix B and assigning them specific possession values will help ensure that new radiopharmaceuticals are subject to appropriate, individualized decommissioning funding requirements rather than generic default requirements. A revision of Appendix B also provides an opportunity to address naturally-occurring and accelerator-produced radioactive materials, as envisioned by the Energy Policy Act of 2005.

Better risk-informing Appendix B is a worthwhile goal. This effort may increase some isotope possession values while decreasing others. As a result, some licensees may have reduced financial assurance obligations while others may become subject to new or additional financial assurance requirements. Those are the natural consequences of a more risk-informed approach. In the paper, the NRC staff mentions that it "will consider measures to compensate for the adverse effects of smaller new Appendix B possession values" and "will consider options to ensure that decommissioning funding requirements are not unjustifiably increased even if smaller values result." The staff suggests that it could arbitrarily "increase the corresponding multiplier values ... by an order of magnitude sufficient to compensate for the smaller new Appendix B possession values." To be clear, that kind of approach would be antithetical to an effort to better risk-inform Appendix B. There is no point in developing more risk-informed possession values if the staff is going to purposefully avoid the regulatory impact of those values by arbitrarily weakening the resulting decommissioning funding requirements. The NRC staff should not pursue this flawed concept in the rulemaking.

With this caveat, I approve initiating the recommended rulemaking and granting the petition for rulemaking. I also approve publication of the *Federal Register* notice announcing this decision, subject to the attached edits.

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

JMB edits

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. 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 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: 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

SUPPLEMENTARY INFORMATION:

- I. Summary of the Petition
- II. Background
- III. Discussion
- IV. Public Comments on the Petition
- V. Reasons for Consideration
- VI. Availability of Documents
- VII. Conclusion

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).¹ On August 23, 2017, the NRC published a notice of docketing and request for comment on the petition.

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 Licensing of Byproduct Material," to ~~specifically~~ add appropriate unlisted radioisotopes and their corresponding activity possession values. The requirements in part 30's § 30.35, "Financial Assurance and Recordkeeping for Decommissioning," refer to the list in appendix B to enable licensees to determine their need for decommissioning financial assurance for sealed and unsealed radioactive materials. Licensees using isotopes not specifically listed in this appendix must use generic default values that the petitioner believes result in ~~unnecessarily stringent~~~~overly burdensome~~ requirements.

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.

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 isotopes] 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 materials (NARM). A significant number of medical isotopes are accelerator-produced. Although the NRC did update schedule B of part 30 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 with a half-life greater than 120 days, a licensee must multiply the appendix B value for that isotope by the applicable 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 funds 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 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.² 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 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, the licensee must provide \$1,125,000. To possess more than 100,000 times the appendix B value, the licensee must provide a DFP that requires an amount based on the license's possession limit for the subject isotope. For isotopes in the form of plated foils or sealed sources, a licensee must provide \$113,000 in financial assurance for decommissioning to possess more than 10 billion times the appendix B value for the isotope, and a DFP to possess more than a trillion times the appendix B value.

Appendix B also includes possession values for isotopes not specifically listed. Known as the "default" possession values, these are 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 isotopes that are in unsealed form and

~~2 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.~~

decommissioning funding requirements by users of other unlisted isotopes. As noted in Section IV. below, commenters have identified several isotopes with actual or potential medical applications that are or could be negatively affected because these isotopes 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 account for an increasing number of medical uses.

~~Second, t~~The petitioner's ~~argues second reason for rulemaking arises from its argument~~ that the default possession values for isotopes 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 argument for rulemaking cites the time and cost impacts of needing to request and process exemptions from these requirements case-by-case. 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."

IV. Public Comments on the Petition

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. 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 ~~costburden~~ for those possessing accelerator-produced isotopes "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 ~~provideconsiderthat~~ radiopharmaceuticals ~~withdeserve~~ 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 isotopes 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 isotopes in appendix C to part 20 on labeling.

On other factors to take into account in setting new appendix B possession values, two commenters recommended similar sets of considerations. These included the physical and chemical form and half-life of the isotope and its progeny, and the disposal pathway for these isotopes 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 radioisotopes in different areas of their facilities, and that some of these isotopes, 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 radioisotopes 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 isotopes 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 isotopes (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 isotopes could effectively exempt from needed regulation industrial wastes containing those isotopes. 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 isotopes, 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 the ~~several~~ 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 isotopes. ~~Second, r~~Rulemaking 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~~ 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~~icient~~ 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-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 Ge-68 generator-supported Ga-68 imaging, Lu-177 radiotherapy, and other emerging medical and industrial technologies that depend on unlisted isotopes ~~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 isotopes in a single comprehensive rulemaking would minimize the need for additional rulemakings in the future when new applications are developed for radioisotopes 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.