

NUCLEAR REGULATORY COMMISSION

10 CFR Part 30

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

Naturally-Occurring and Accelerator-Produced Radioactive Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; notice of docketing and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received a petition for rulemaking from Matthew McKinley on behalf of the Organization of Agreement States (OAS) (the Petitioner) dated April 14, 2017, requesting that the NRC revise its regulations to add radionuclides and their corresponding activities to the list of “Quantities of Licensed Material Requiring Labeling.” The petition was docketed by the NRC on June 21, 2017, and has been assigned Docket No. PRM-30-66. The NRC is examining the issues raised in PRM-30-66 to determine whether they should be considered in rulemaking. The NRC is requesting public comment on this petition.

DATES: Submit comments by **[INSERT DATE THAT IS 75 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for 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.

- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677. For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: 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. Obtaining Information and Submitting Comments

A. Obtaining Information

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

- **Federal rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2017-0159.

- **NRC's Agencywide Documents Access and Management System (ADAMS):**
You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then 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, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- **NRC's 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.

B. Submitting Comments

Please include Docket ID NRC-2017-0159 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into

ADAMS.

II. The Petitioner

The membership of OAS consists of state radiation control directors and staff from the 37 Agreement States who are responsible for the implementation of their respective Agreement State programs. The purpose of the OAS is to provide a mechanism for the Agreement States to work with each other and with the NRC on regulatory issues associated with their respective agreements.

III. The Petition

The petitioner request that the NRC amend its existing regulations in appendix B to part 30 of title 10 of the *Code of Federal Regulations* (10 CFR), to specifically add the appropriate radionuclides and their corresponding activities to the list of “Quantities of Licensed Material Requiring Labeling.” The requirements in 10 CFR 30.35, “Financial Assurance and Recordkeeping for Decommissioning,” refer to the list in appendix B to 10 CFR part 30 to determine the need for a decommissioning funding plan and the amount of financial assurance required for sealed and unsealed sources. The petition states that the list in appendix B to 10 CFR part 30 is outdated and does not include conforming updates resulting from the 2005 amendment of the Energy Policy Act. The OAS petition is available in ADAMS under Accession No. ML17173A063.

IV. Discussion of the Petition

The petitioner believe that patient health and safety is being compromised due to licensing delays of important diagnostic and therapeutic products that utilize radioisotopes that are not listed in the appendix B table in 10 CFR part 30. The petitioner assert that when the Energy Policy Act was amended in 2005 to include discrete naturally-occurring and accelerator-produced radioactive materials (NARM) into the definition of byproduct material, that 10 CFR part 30, schedule B, exempt quantities for licensing was updated to include certain NARM isotopes. They note however that 10 CFR part 30, appendix B, "Quantities of Licensed Material Requiring Labeling," which is the driver for the decommissioning funding plan and financial assurance, was not updated. As a result, the OAS believes that state regulators are forced to apply overly burdensome financial assurance obligations or evaluate on a case-by-case basis special exemptions for new products. They feel that this results in delays in using these improved products or discourages their development.

The petitioner point out that the NRC's Advisory Committee on the Medical Uses of Isotopes evaluated the financial assurance requirements for germanium-68 generators and concluded that these requirements were too restrictive and would prevent or deter the use of promising gallium-68 diagnostic imaging agents for patients. Authorization for granting specific exemption from the decommissioning funding plan requirement for Ge-68/Ga-68 generators was developed. A rulemaking action to provide a permanent regulatory solution has been initiated; however, the petition notes that the OAS is disappointed that the rule would address only this one isotope.

Rather than issue exemptions on a case-by-case basis, the petitioner assert the more appropriate way to address the inconsistency is to amend appendix B to 10 CFR part 30 to add appropriate radionuclides and their corresponding activities. The petition states that the failure to address this inconsistency puts an undue hardship on certain licensees with little or no radiation safety benefit, discourages the development of new beneficial products, and negatively impacts patient care.

V. Request for Comment

The NRC staff is requesting public comment on the following specific questions:

1. What products or technologies, other than the germanium-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 of 10 CFR part 30?
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 naturally-occurring or accelerator-produced radioactive materials (NARM).
3. Given 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 of 10 CFR part 30?
4. Does this petition raise other issues not addressed by the questions above about labelling 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?

Dated at Rockville, Maryland, this 16th day of August, 2017.

For the Nuclear Regulatory Commission.

/RA/

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