PRM-30-66
82FR39971

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PUBLIC SUBMISSION

As of: 11/6/17 11:04 AM
Received: November 03, 2017
Status: Pending_Post
Tracking No. 1k1-8zl1-hkjz
Comments Due: November 06, 2017
Submission Type: Web

Docket: NRC-2017-0159
Naturally-Occurring and Accelerator-Produced Radioactive Materials

Comment On: NRC-2017-0159-0002
Naturally Occurring and Accelerator-Produced Radioactive Materials; Petition for Rulemaking; Notice of Docketing and Request for Comment

Document: NRC-2017-0159-DRAFT-0007
Comment on FR Doc # 2017-17690

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General Comment

CORAR is submitting comments to Docket ID NRC-2017-0159. Please see attached

Attachments

2017-11-03 CORAR Comments to NRC-2017-0159

CORAR

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Michael J. Guastella, MS, MBA
Executive Director

November 3, 2017

Secretary
U.S. Nuclear Regulatory Commission
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ATTN: Rulemakings and Adjudications Staff

RE: DOCKET ID NRC-2017-0159, NATURALLY-OCCURING AND ACCELERATOR - PRODUCED RADIOACTIVE MATERIALS; FEDERAL REGISTER VOL. 82, NO. 162; AUGUST 23, 2017

I am writing today on behalf of the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) to provide comments regarding the Organization of Agreement States (OAS) petition (No. PRM-30-66) requesting that Appendix B of Title 10 of the Code of Federal Regulations, Part 30 (10 CFR 30), *Quantities of Licensed Material Requiring Labeling*, be amended as published in the *Federal Register*, Vol. 82, No. 162, published on August 23, 2017 for Docket ID NRC-2017-0159. CORAR is an industry association of firms that manufacture diagnostic and therapeutic radiopharmaceuticals, radionuclides, and other radioactive products primarily used in medicine and research, and also includes firms that operate nuclear pharmacies that prepare and dispense radiopharmaceuticals in patient-ready doses for administration to patients in health care facilities.

CORAR believes that there is an urgent need to update Appendix B of 10 CFR 30 and supports the OAS petition and their statements that, "… the more appropriate way to address the inconsistency in Appendix B is to amend it to include appropriate nuclides and their corresponding activities, as determined by a rulemaking working group." This will address the missing key radionuclides in Appendix B needed to advance medical research and patient care. Additional comments, addressing the questions NRC posed in NRC-2017-0159 are enclosed to this letter.

Respectfully,

Michael J. Guastella
Executive Director

MJG:mdl
Enclosure

cc: Council on Radionuclides and Radiopharmaceuticals, Inc.
Society of Nuclear Medicine and Molecular Imaging
American College of Radiology

Council on Radionuclides and Radiopharmaceuticals, Inc.

COMMENTS ON NATURALLY-OCCURING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS AS REQUESTED ON DOCKET ID NRC-2017-0159 PUBLISHED ON FEDERAL REGISTER VOL. 82, NO. 162

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?**

The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) undertook a review of current and upcoming radionuclides undergoing research and medical evaluation. Based on that review, CORAR determined there are multiple radionuclides with half-lives greater than 120 days not currently listed in Appendix B of the Title 10 of the Code of Federal Regulations, Part 30 (10 CFR 30). A list of these radionuclides is presented in the table below. The list is not all inclusive. However, these are the radionuclides identified by CORAR stakeholders as primary concerns.

Radionuclide	Half-Life (days)
Na-22	949
Al-26	2.6×10^{8}
Si-32	5.8×10^{4}
Ti-44	2.2×10^{4}
Ge-68	270.8
Cd-109	462
Lu-177m	160.7
Th-228	693.5

As research and clinical evaluations of new radionuclides for diagnostic and therapy continue, it is easy to imagine that each of the radionuclides listed above could be subject to a similar product specific review similar to that performed by the U.S. Nuclear Regulatory Commission (NRC) for germanium-68/gallium-68 (Ge-68/Ga-68) generators. Rather than case-by-case reviews, CORAR strongly believes the best solution is to amend Appendix B of 10 CFR part 30 to capture appropriate radionuclides and their corresponding activities, as determined by a rulemaking working group.

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).**

CORAR offers the description and example offered by the Advisory Committee on the Medical Use of Isotopes (ACMUI) and its Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP)

Subcommittee in their Draft Report[1] with regard to hospital licenses. In the report, the ACMUI subcommittee discussed an East Coast Medical Center attempt to acquire a Ge-68/Ga-68 generator for clinical investigation. Due to extensive use of radiopharmaceuticals in several nuclear medicine clinical areas, and the financial requirements of a potential DFP, this Medical Center found that the costs to fund their potential DFP would have been onerous. In addition, the development of their potential DFP was estimated to require over 170 man-hours from the Radiation Safety personnel. The financial assurances in the form of a bond would need to be purchased to cover the decommissioning expenses of over one million dollars. As a result, they reversed their decision to acquire the necessary financial assurances for a DFP. This Medical Center did acquire a Ge-68/Ga-68 generator of less than 10 mCi of activity. Unfortunately, the Medical Center was not able to conduct research with Ge-68/Ga-68 in human patients.

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?**

CORAR strongly agrees with ACMUI's approach for Ge-68 in its subcommittee draft report[1] to establish a possession limit similar to comparable radionuclides already listed in 10 CFR 30, Appendix B. The same approach may be extended to the radiopharmaceuticals listed in Question 1.

Additional factors may also be considered when establishing possession limits:

- Physical and chemical form of the radionuclide and its progeny
- Half-life of the radioactive progeny
- Applicable risk-based regulations
- Considerations related to final decommissioning status

The form of the radioactive parent, its progeny and half-lives of the progeny daughters are important factors to determine if the radiopharmaceutical would be in a form that could increase radiation risks from exposure at the time of decommission. For example, Ge-68/Ga-68 contained in a generator column may be considered not readily dispersible since it requires the elution of the generator to release the desired material. Even when eluted, the Ga-68 solution is contained in sealed vials for clinical use; thus, limiting the potential for dispersing as airborne material. The half-life of Ga-68 (68 minutes) is low enough that it may be decayed-in-storage prior to being disposed of as radioactive waste or via release to sewers in accordance with 10 CFR 20, Subpart K, decreasing potential decommissioning risks.

Specific decommissioning concerns may be related to the potential residual radioactivity levels at the time of decommissioning. For example, if Ge-68/Ga-68 generators are retuned to manufacturers upon use for disposal as radioactive waste. The radioactive material would not be present in the facility at the time of decommissioning to pose a risk to the final release status. Thus, financial assurance for decommissioning may not be necessary. In similar form, radiopharmaceuticals used in clinical settings, whether for research, diagnostic or therapy, are typically injected into patients. At that time, the radionuclide is contained in the subjects or patients and not readily dispersible unless excreted by the subject or patient. In those instances, it would be an onerous regulatory and financial requirement for the medical facility to have a DFP for the small residual radio-contaminant of a U.S. Food and Drug Administration approved product that is left in a vial (or syringe) after patient administration and does not significantly increase the risk of exposure at the time of decommissioning.

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[1] ACMUI 2010. Advisory Committee on the Medical Use of Isotopes. Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) Subcommittee. Draft Report. ADAMS no. ML ML15209A681. Available at: https://www.nrc.gov/docs/ML1520/ML15209A681.pdf

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?**

   CORAR believe that the corrective actions may require rulemaking.

   This petition raises inconsistencies between 10 CFR 20 and 10 CFR 30 for risk-based decision making. For example, of the radionuclides identified in Question 1 of this letter, the following are listed in 10 CFR 20, Appendix C: Na-22, Si-32, Ti-44, Ge-68, Cd-109 and Lu-177m. In addition, consider that section 20.2201 of 10 CFR 20, *Reports of theft or loss of licensed materials* is based on the risk of exposure and potential doses to members of the general public in the event of theft or loss of license materials. Similar limits may be applicable to those radionuclides listed in Question 1 that do not result in significant risk of exposure at the time of decommissioning.

   Therefore, as an alternative to amending Appendix B of 10 CFR part 30, CORAR encourages the NRC to evaluate the withdrawal of this appendix, as the basis for determining possession limits that result in a DFP requirement. In its place, CORAR suggests that the NRC adopt Appendix C of 10 CFR Part 20 as the basis for DFP determinations in the future. Additionally, Appendix C is much more current than Appendix B of 10 CFR 30.

In conclusion, CORAR agrees with the OAS that there is a need to amend appendix B of 10 CFR Part 30, as determined by a rulemaking group. We believe this is necessary to continue to foster research and improve patient access to innovative radionuclide diagnostic and therapeutic procedures.