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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-0011

Comment on FR Doc # 2017-17690

Submitter Information

Name: Melissa Martin

Submitter's Representative: Richard Martin

Organization: American Association of Physicists in Medicine (AAPM)

General Comment

See attached file(s)

Attachments

AAPM Final NARM NRC Comment

November 6, 2017

Annette L. Vietti-Cook
Secretary for the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Naturally-Occurring and Accelerator-Produced Radioactive Materials (Docket No. PRM-30-66; NRC-2017-0159)

Dear Ms. Vietti-Cook:

The American Association of Physicists in Medicine (AAPM)¹ is pleased to submit comments to the U.S. Nuclear Regulatory Commission (NRC) regarding the Organization of Agreement States' (OAS) petition for rulemaking requesting that the NRC revise its regulations to add radionuclides and their corresponding activities to the list of "Quantities of Licensed Material Requiring Labeling" in Appendix B of Part 30. The AAPM commends the NRC on its work in crafting the specific exemption from the decommissioning funding plan requirement for Ge-68/Ga-68 generators. The AAPM further commends the NRC for its efforts to engage stakeholders on this issue.

General Remarks

¹ The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography, CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various state regulatory agencies. AAPM represents over 8,700 medical physicists.

The NRC is seeking public comment on a petition for rulemaking submitted by the Organization of Agreement States (OAS). The petition calls for editing Appendix B of Part 30 to include previously-unlisted naturally-occurring and accelerator-produced radioactive materials (NARM) radionuclides to avoid a default possession threshold for unlisted radionuclides that would require a decommissioning funding plan (DFP).

The OAS believes that patient health and safety may be compromised by licensing delays of diagnostic and therapeutic products that utilize radioisotopes that are not listed in Appendix B Part 30. The OAS also expresses concern that development of innovative products might be discouraged. The NRC asks stakeholders to identify products or technologies that could be adversely affected because the radioactive materials they require are not currently listed in Appendix B Part 30.

Impacted Products and Technologies

AAPM is not aware of any radionuclide with a half-life greater than 120 days, other than Ge-68, that is currently used (or has the potential for future use) in medicine or research that would trigger a DFP. AAPM believes, however, that other radionuclides that may in the future impact medical use isotopes will be parent isotopes for generators like Ge-68/Ga-68, or long-lived contaminants that might be present in a radionuclide. For instance, Lutathera (lutetium(¹⁷⁷Lu) oxodotreotide), used to treat tumors, may contain Lu-177m (160.44 d) contaminant, and a regulator may seek to include such a contaminant in a license.

Decommissioning Financial Assurance and Labeling Values

AAPM acknowledges NRC's interest in requiring medical use licensees to develop DFPs and provide decommissioning financial assurance. AAPM urges the NRC to ensure that the regulatory framework for the decommissioning financial assurance reflects current use of listed radionuclides and does not unreasonably burden the licensee that depends on

naturally-occurring or accelerator-produced radioactive materials (NARM) to diagnose or treat patients.

The ACMUI wrote about the origins of the Part 30 App B table in its “Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) - Final Report”² cited in the OAS petition. In the report’s addendum, the ACMUI provides insight into development and substantiation of labeling values.

The ACMUI noted that prior to 1994, Appendix B Part 30 did not exist. Instead, the requirements in § 30.35 referenced the old Appendix C Part 20, which first appeared in the regulations in 1970. The ACMUI further noted that the current decommissioning funding plan (DFP) regulations in section § 30.35 are based on values that were established 45 years ago stemming from the International Commission on Radiological Protection Committee II (ICRP 2) recommended values for maximum permissible air concentrations.

Accordingly, the AAPM recommends a more comprehensive updating of NARM labeling values used in determining DFP and financial assurance requirements. AAPM suggests the NRC consider eliminating Appendix B Part 30 and instead reference in Part 30 an updated Appendix C Part 20. AAPM recommends that the NRC finish what it did not finish when it updated Appendix C Part 20 in 1994. An updated Appendix C would provide a more comprehensive listing of radionuclides, presenting labeling values with greater viability and practicality.

Conclusion

The AAPM recommends that the NRC consider an approach broader than merely adding one or two radionuclides to Appendix B Part 30. The AAPM urges the NRC to finish what it did not finish when it updated Part 20 Appendix C in 1994; eliminate the current Appendix B Part 30; and reference an updated Appendix C Part 20.

² ML15231A047

Thank you for this opportunity to comment. If you have any questions or require additional information, please contact Richard J. Martin, JD, Government Relations Specialist, at 571-298-1227 or Richard@aapm.org

Sincerely,

A handwritten signature in black ink that reads "Melissa C. Martin". The signature is written in a cursive style with a large, prominent "M" at the beginning.

Melissa Carol Martin, MS, FAAPM, FACMP
President, AAPM