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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

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General Comment

See attached file(s)

Attachments

Cardinal Health Comments NRC appendix B

November 3, 2017

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001
ATTN: Rulemakings and Adjudications Staff

Re: **Docket No. PRM–30–66; NRC–2017–0159**

Cardinal Health respectfully submits the following comments in accordance with Docket No. PRM–30–66; NRC–2017–0159 concerning revision of 10 CFR Part 30 to add radionuclides and their corresponding activities to the list of "Quantities of Licensed Material Requiring Labeling."

Cardinal Health wishes to express support for the petitioner's request to update appendix B to 10 CFR part 30 to include isotopes such as germanium-68. Our comments below are in response to the questions posed by NRC staff in the Federal Register notice:

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?

   Cardinal Health requests that NRC consider also including the following radioisotopes in appendix B of 10 CFR part 30, because products based on or associated with the use of these radioisotopes could be negatively affected:
   - Cobalt 57
   - Actinium 227
   - Thorium 227
   - Thorium 228
   - Lutetium 177m

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).

   - The current NRC regulatory framework has slowed development and use of certain new radiopharmaceuticals, such as gallium-68 based radiopharmaceuticals (since the parent isotope is germanium-68). Problems with the current regulatory framework include:

    - Undue financial assurance burdens are placed on licensees, which potentially slows and discourages development and use of these products.
    - Navigating the decommissioning financial assurance process with regulators creates unnecessary delays, which also discourages development and use of these products.
- These delays impact the availability of these products to patients, thus impacting patient care if a patient does not have access to the best and current technology for diagnosing or treating their particular disease state.
- Following the expansion of the NRC's regulatory authority over accelerator produced materials, appendix B to 10 CFR part 30 did not fully reflect typical accelerator produced isotopes, such as Co-57. This in turn led to the potential for an increased burden for financial assurance for those possessing accelerator produced isotopes, whether as part of a particular product or as part of the activation of accelerator components.
- This 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 amendment requests.

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?

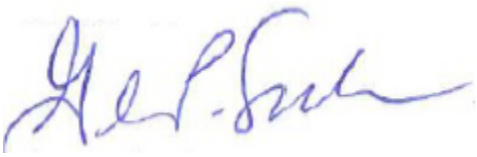
   The NRC should take into account factors such as:
   - The physical and chemical form
   - The configuration and potential dispersability
   - The half life
   - The type of radiation emitted
   - Typical disposal pathways used by the type of licensee requesting possession of the material. For example, a nuclear pharmacy possessing a Ge-68/Ga-68 generator disposes of the generator simply by returning it to the manufacturer, not by seeking burial at a low level radioactive waste site. The nuclear pharmacy using a fully-assembled generator has a different level of risk than the manufacturer of that generator.

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?

   The NRC should also consider:
   - aligning appendix B to 10 CFR part 30 and appendix C of 10 CFR part 20 to reduce differences between two appendices that pertain to "labeling".
   - that nuclides possibly used in diagnostic or therapeutic drugs with a half life less than 120 days may have a contaminant with a half life greater than 120 days. Appendix B to 10 CFR part 30 should also reflect those potential contaminants.

The petition and these issues will likely require a rulemaking process to address appendix B of 10 CFR part 30. Other regulatory solutions, such as the NRC issuing broad exemptions, may result in unnecessary delays and uncertainty with the regulatory process, and are not likely to be tenable.

Sincerely,



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