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November 20, 2017

Secretary, US Nuclear Regulatory Commission  
Washington, DC 20555-0001  
Rulemaking.comments@nrc.gov

ATTN: Rulemakings and Adjudications Staff  
Docket ID: NRC-2017-0159

We are writing today in support of the petition for rulemaking from the Organization of Agreement States to revise 10 CFR 30, Appendix B to add additional radionuclides to the list of "Quantities of Licensed Materials Requiring Labeling" which affects the need for a decommissioning funding plan and financial assurance amounts. The request for comment on this petition was originally posted in the Federal register on August 23, 2017 and more recently on November 6, 2017. Our responses to your specific questions are listed below.

*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?*

As the request notes, the most immediate need for regulatory relief is for the germanium-68 generator. As the NRC has already noted through the development of the Ge-68/Ga-68 generator licensing guidance work, the lack of a 10 CFR 30 Appendix B listing for Ge-68 has caused additional work for facilities that utilize the Ge-68 generators for medical use of Ga-68 labeled imaging agents. It has caused additional regulatory burden in license modifications and efforts to establish disposal agreements with manufacturers simply because there is no established Appendix B value (which we believe should be established at least at 10 microcuries if not higher as compared to comparable radionuclides).

Regarding additional radionuclides, the nuclide that comes to mind is lutecium-177m. Lutecium-177m is a byproduct of the production of lutecium-177, which is currently used in medical research with IRB approval. This may soon become widely used for radiopharmaceutical therapy pending approval from the Food and Drug Administration (FDA). While Lu-177m is only a small fraction of the produced Lu-177 (reported to be less than 0.02-0.04% at calibration), administered dosages of 200 mCi of Lu-177 could amount to significant levels of Lu-177m within a single administration (up to 80 microcuries per individual administration).

Without a 10 CFR 30 Appendix B quantity, the brief possession of two individual dosages of Lu-177 could result in the need for a decommissioning financial assurance because one must use the default 0.1 microcurie Appendix B value for determining decommissioning financial assurance requirements (possession of 100 microcuries would require \$225,000 financial assurance).

*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).*

As discussed above, the use of the Eckert and Ziegler germanium-68 generator system has created additional hurdles for the regulated community in order to use the device. We also have discussed above how the pending approval of Lu-177 by the FDA may also cause the need for financial assurance due to the Lu-177m contaminant within the radiopharmaceutical therapy agent. The result would be that smaller facilities (nuclear medicine only licensees) that do not currently require financial assurance will likely need to establish \$225,000 decommissioning financial assurance and larger facilities may be bumped into another financial assurance or decommission funding plan category simply because they are using Lu-177 (and hence, will possess some Lu-177m briefly).

*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?*

Since 10 CFR 30 Appendix B is titled "Quantities of Licensed Materials Requiring Labeling", and 10 CFR 20 Appendix C is also titled "Quantities of Licensed Material Requiring Labeling", We wonder why there are two identically titled regulations that have different values. Possibly 10 CFR 30 Appendix B can be re-titled to indicate its principle use within part 30 – determining decommissioning financial assurance requirements. Possibly 10 CFR 30 Appendix B might be re-titled "Quantities of Licensed Materials Related Important for Decommissioning Funding Purposes" or something like that. This would prevent two identically titled parts of the rulemaking from conflicting with each other.

As for the determination of the 10 CFR 30 Appendix B, the values in 10 CFR 20 Appendix C make a good starting point. We note that Susan Lanhorst, PhD, CHP makes this same argument in her comments dated November 6, 2017 and support that approach in general. However, we believe additional items may need to be considered.

One specific parameter that should be considered would be medical radionuclide generator systems such as the Ge-68 generator. By design, medical radionuclide generators are intended to maintain the parent nuclide within the generator device with minimal release (breakthrough) within the daughter product elution. The parent material is typically either a solid or material trapped on a large particle / resin to prevent release. As long as the generator elution test results are within manufacturer's specifications, the generators should be treated as a sealed device for decommission funding plan and financial assurance purposes. We recommend that for medical

use radiopharmaceutical generators the 10 CFR 30 Appendix B values be increased by a factor of 10. Justification is provided within ANSI/HPS N13.39<sup>1</sup>, which provides release factors for a variety of physical forms of radioactive materials. The release factor given within Table A.1 for liquid form is 0.01. For solids and material trapped on large particles (e.g. resins) the release factor is 0.001, or 10 times less than for liquids. As an example, for Ge-68/Ga-68 generators we are recommending that the Appendix B value be increased to 100 microcuries.

We are certain there are other factors to consider when determining 10 CFR 30 Appendix B quantities, but special consideration for appropriately functioning medical radionuclide generators needs to be addressed. Regardless, the NRC should establish values for all radionuclides with half-life greater than 120 days since it is hard to predict where the next medically useful radionuclide will come from in the future.

*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?*

We are not aware of any additional issues that need to be considered at this time.

If you have any questions regarding this letter, please feel free to contact me at [sturchio.glenn@mayo.edu](mailto:sturchio.glenn@mayo.edu).

Sincerely,



Glenn M. Sturchio, PhD, CHP  
Radiation Safety Officer  
Secretary, Radiation Safety Committee

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<sup>1</sup> ANSI/HPS N13.39-2001, Design of Internal Dosimetry Programs, May 24, 2001, American National Standards Institute, Inc.

**From:** Sturchio, Glenn M., Ph.D.  
**To:** [RulemakingComments Resource](#)  
**Cc:** [Sturchio, Glenn M., Ph.D.](#)  
**Subject:** [External\_Sender] Comment on Docket ID: NRC-2017-0159  
**Date:** Monday, December 04, 2017 2:17:28 PM  
**Attachments:** [Comment to NRC-2017-0159.pdf](#)

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Please find attached Mayo Clinic comments in support of the petition for proposed rulemaking from the Organization of Agreement States to revise 10 CFR 30, Appendix B.

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