Organization of Agreement States

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April 14, 2017

Ms. Vietti-Cook, Secretary
US Nuclear Regulatory Commission
Washington D.C. 20555-0001

Attention: Rulemakings and Adjudications Staff

Re: Petition for Rulemaking: Revision of 10 CFR 30 Appendix B

Dear Secretary Vietti-Cook:

The Organization of Agreement States (OAS) respectfully submits this petition for rulemaking. As per 10 CFR 2.801(c)(i), you may contact me at matthewww.mckinley@ky.gov regarding this petition.

The OAS believes that patient health and safety is being compromised due to licensing delays of important diagnostic and therapeutic products that utilize radioisotopes not listed in the 10 CFR 30 Appendix B table.

The requirements of 10 CFR 30.35, Financial Assurance and Recordkeeping for Decommissioning, refer to 10 CFR 30 Appendix B to determine the need to submit a decommissioning funding plan (DFP) and the amount of Financial Assurance (FA) required for sealed and unsealed sources. When the Energy Policy Act was amended in 2005 to include discrete naturally occurring and accelerator produced (NARM) in the definition of byproduct material, 10 CFR 30 Schedule B, exempt quantities for licensing, was updated to include certain NARM isotopes; however, Appendix B, Quantities of Licensed Material Requiring Labeling, which is the driver for DFPs and FA was not.

Radionuclides, such as germanium-68 (Ge-68), cobalt-57 (Co-57), and other nuclides that are not included in Appendix B must be classified as either "Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition" or "Any radionuclide other than alpha emitting radio-nuclides, not listed above or mixtures of beta emitters of unknown composition". A comparison of these generic categories in Appendix B demonstrates that these values are two of the most restrictive in the table. Therefore, regulators are forced to evaluate new products against these criteria and apply overly burdensome financial assurance obligations or to evaluate case by case special exemptions. At best, this

results in delays in utilizing these improved products and at worst, discourages their development.

In STC-16-065, the NRC states that it realizes the burden, quality of care, and patient health and safety issues as related to the Germanium/Gallium generator. The Advisory Committee on the Medical Uses of Isotopes evaluated the financial assurance requirement for Ge-68 generators and concluded that these requirements were too restrictive and would prevent or deter the use of promising gallium-68 (Ga-68) diagnostic imaging agents for patients (ML15231A047). Concerns were raised with respect to the resources needed to develop and maintain a DFP for the Ge-68/Ga-68 generator. After analysis, NRC staff agreed the DFP requirement could impede or limit patient access to the radiopharmaceuticals developed from this generator. Since there is no reasonable basis to impose the restrictive limits from Appendix B, and in an effort to facilitate the beneficial use of this radiopharmaceutical, authorization for granting specific exemption from decommissioning funding plan requirement for Ge-68/Ga-68 generators was developed. NRC staff determined this exemption will ensure public health and safety, at the same time allowing access to the radiopharmaceuticals developed from this generator until a permanent regulatory solution is reached through rulemaking. And although a direct final rule process has been initiated, the OAS members were disappointed that it would only address this one isotope.

As you know, there are dozens of radiopharmaceuticals containing NARM and other isotopes that are, or have been used for their respective benefits. Based on the product specific solution to the Ge68/Ga68 issue, it is realistic to consider the possibility of multiple specific solutions for other radionuclide containing products meeting similar regulatory restrictions. Further, development of new products could be discouraged due to these obstacles, diminishing the possibility of new innovative and beneficial options in both medical and industrial applications.

Rather than issuing exemptions on a case by case basis, the more appropriate way to address the inconsistency in Appendix B is to amend it to add appropriate nuclides and their corresponding activities, as determined by a rulemaking working group. NRC's continued 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.

The OAS membership supports this petition and the proposed solution. Please contact me if you have any questions.

Sincerely,

Matthew W. McKinley
OAS Chair
Radiation Health Program Administrator
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