# PUBLIC SUBMISSION

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## Submitter Information

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## General Comment

The Conference of Radiation Control Program Directors (CRCPD), H-47 Committee on Nuclear Medicine, respectfully offers comments responsive to the Commission's request for comments regarding the Organization of Agreement States' petition for rulemaking, Docket ID NRC-2017-0159.

The NRC should consider the following in formulating a solution to the issue identified by the Agreement States:

1. The NRC liaison to the US Food and Drug Administration (FDA) should contact the FDA to inquire about pending or anticipated drug applications for radiopharmaceuticals or radiopharmaceutical generators that may contain long lived (<120-day half-life) isotopes that are not currently listed in Appendix B to 10 CFR 30. Contaminate isotopes should also be considered.

2. It might be necessary to add lutetium 177m to Appendix B. This long-lived contaminant can be present in lutetium 177 (Lu-177) dotatate, dependent on the production method used to

create Lu-177. (Lu-177 dotatate is currently in use to treat neuroendocrine carcinoma.) The presence of Lu-177m in conjunction with possession of other isotopes has the potential to trigger the requirements for a decommission funding plan (DFP) and financial assurance (FA).

3. Both Appendix C to 10 CFR 20 and Appendix B to 10 CFR 30 are titled "Quantities of Licensed Material Requiring Labeling". The Part 20 list was revised in alignment with the expansion of the definition of "byproduct material" as necessary to implement the 2005 changes to the Energy Policy Act. However, the Part 30 Appendix was not amended. Although sharing a common name, many of the values for isotopes listed in the Part 30 Appendix differ by an order of magnitude (higher or lower) from the quantities for the same isotopes listed in the Part 20 Appendix. The derivation of the Part 20 values is stated in the footnote to Appendix C, however the derivation of the values in the Part 30 Appendix is not provided in Part 30. The NRC should consider amending Part 30 to provide the formula(s) to be used to derive Part 30 Appendix B quantities for unlisted isotopes. This should be in place of the default value of 0.1 for the category other than alpha emitters not listed in the Appendix. Doing so will alleviate the need for subsequent amendments to Appendix B and minimize negative impact (or potential impact) on medical licensees and patient care.

4. The requirements in 10 CFR 30.35 effectively specifies two physical forms, unsealed byproduct material, and sealed sources or plated foils, with corresponding multipliers of 105 and 1012, respectively. In the case of a Germanium 68/Gallium-68 generator the parent isotope is not contained in a sealed source, rather it is bonded to a solid matrix within the generator. The column (containing Ge-68) and internal components are not accessed or serviceable by the user. Ge- 68 is not handled or utilized outside of the generator. However, there is no provision or "credit" for byproduct material that is bonded to a matrix. The threat of contamination from an isotope bound to a solid matrix within a controlled system is significantly less than that which is posed by benchtop use or use in a manufacturing processes. The NRC should apply a risk-informed approach to develop a more realistic multiplier for byproduct material contained in an FDA approved generator system such as the Ge-68/Ga-68 generator. Use of a multiplier such as 107 would reflect a more realistic risk-based scenario for possession of a Ge-68/Ga-68 radiopharmaceutical generator and would effectively eliminate the need for a DFP and FA.