UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 3, 2020

Bruce S. Manheim Jr
1875 Pennsylvania Avenue, NW
Washington, DC 20006

SUBJECT: LUTETIUM-177 LICENSING DETERMINATION

Dear Mr. Manheim:

Thank you for writing to the U.S. Nuclear Regulatory Commission (NRC) staff concerning the production of lutetitium-177 (Lu-177), specifically the production process which introduces an impurity, metastable Lu-177 (Lu-177m). In your letter, dated October 7, 2019, you requested the NRC revise and reissue the Lu-177 licensing determination memorandum published on June 1, 2018 (Agencywide Documents Access Management System Accession No. ML18136A824) to further clarify the two distinct processes that manufacturers employ to produce Lu-177 and the proper disposal of Lu-177m waste. The NRC evaluated your request and has determined that no additional clarification is required. In the enclosure to the licensing determination memorandum entitled, "Radiation Safety Considerations for Lutetium-177 (Lu-177)," the NRC staff provided information that addresses all your requests. The enclosure informs licensees of the different processes that manufactures use to produce Lu-177 and provides licensees with information on how to properly dispose of Lu-177 waste, if present. The existing Lu-177 licensing determination provides a performance-based regulatory approach that doesn't impose extra burden and allows Lu-177 to be treated as other radioisotopes with similar characteristics.

The guidance provided in the enclosure to the memorandum is similar to other NRC guidance for the medical use of radioactive materials where impurities may be detected, such as yttrium-90 (Y-90) microspheres. Due to different manufacturing processes, the activity and radionuclides of the impurities vary for different Y-90 microsphere products, some of which are long-lived (i.e., half-lives of greater than 120 days). As with Y-90, licensees authorized for Lu-177 should be aware that impurities may be present. The NRC does not limit manufacturers to specific manufacturing processes, and it is therefore possible for the activity and types of radionuclide impurities to differ depending on the manufacturing process.

Licensees are responsible to ensure that Lu-177, like Y-90, is handled and disposed of in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20 and Part 35 requirements. Specifically, 10 CFR 35.92 requires that licensees monitor byproduct material with a physical half-life of less than or equal to 120 days at the surface before disposal and determine that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter. Therefore, regardless of the length of time a licensee has allowed the material to decay, a licensee is not permitted to dispose of Lu-177 if radioactivity can be distinguished from the background radiation level with an appropriate radiation detection survey meter. If waste is determined to contain impurities with a physical half-life of greater than 120 days that can be distinguished from the background radiation level

with an appropriate radiation detection survey meter, the licensee must use one or more of the following means to dispose of waste associated with the Lu-177:

- return unused Lu-177 vials to the manufacturer, if the manufacturer is authorized to receive them;
- transfer the Lu-177 to an authorized recipient pursuant to requirements in 10 CFR Part 20 and Part 35; or
- dispose of the material in another manner, pursuant to the requirements in 10 CFR Part 20, Subpart K.

You may consider reaching out to the US Food and Drug Administration with your concerns at the following telephone number: 1 (800) 638-2041 or email: DICE@fda.hhs.gov.

If you have any questions or need additional information, please contact me at: Christian.Einberg@nrc.gov or (301) 415-5422.

Sincerely,

/RA/

Christian Einberg, Branch Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: LUTETIUM-177 LICENSING DETERMINATION DATED: FEBRUARY 3, 2020

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