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

June 21, 2018

ALL AGREEMENT STATES, VERMONT, WYOMING

LICENSING OF LUTETIUM-177 (STC-18-042)

Purpose: To inform Agreement States of the U.S. Nuclear Regulatory Commission (NRC) Lutetium-177 (Lu-177) licensing decision.

Background: On January 26, 2018, the U.S. Food and Drug Administration (FDA) approved a radiopharmaceutical (LUTATHERA®) that uses lutetium-177 (Lu-177) to treat gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Lu-177 has a half-life of 6.7 days and is delivered in a similar manner as other beta-emitting therapy parenteral administrations. Lu-177 has a short penetration radius, which makes it suitable for radioimmunotherapy for smaller tumors like GEP-NETs. Lu-177 has both gamma and beta emissions, allowing for the acquisition of images incidental to the intended therapeutic treatment.

Discussion: The NRC staff reviewed the radiation safety and regulatory aspects (e.g., radionuclide and progeny emissions, radiation detection, monitoring and measurements, authorized user training and experience needs, patient administration and release considerations, dose delivery, and handling and waste disposal) of the medical use of Lu-177 and has determined that the applicable licensing provisions are in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, Subpart E, "Unsealed Byproduct Material – Written Directive Required." The medical use of Lu-177 is similar to other commonly used beta- and photon-emitting therapeutic radiopharmaceuticals.

The NRC staff concluded that physicians approved for the use of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV under 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required" may also be authorized for the medical use of Lu-177. Physicians authorized under 10 CFR 35.396, "Training for the parenteral administration of unsealed byproduct material requiring a written directive," may also be authorized for the medical use of Lu-177.

The NRC staff evaluated waste storage issues when handling Lu-177. Lu-177 waste may be decayed in storage under the performance-based rule in 10 CFR 35.92, "Decay-in-storage." Small quantities of metastable Lu-177 (Lu-177m), with a half-life of 161 days, may be present as a contaminant generated from the production of Lu-177. If present, Lu-177m may contribute approximately 0.02 percent of the total amount of Lu-177. Lu-177m emits low-energy photons and beta emissions that, even in low quantities, are detectable using standard scintillator detectors and Geiger counters. If Lu-177m is detected by appropriate survey methods, then licensees must dispose of the waste material as low-level radioactive waste in accordance with the requirements in 10 CFR Part 20 Subpart K, "Waste Disposal." Further, the licensee would need to develop safe handling and disposal procedures for detectable quantities of Lu-177m.

Additional radiation safety considerations for Lu-177 can be found using NRC's Agencywide Documents Access and Management System Accession No. ML18136A824. If the NRC becomes aware of future developments related to the production, distribution, or medical use of Lu-177 that may negatively impact radiation safety, the NRC staff will consider revisiting this licensing decision for any additional actions.

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