IEMA-OHS
Illinois Emergency Management Agency
and Office of Homeland Security

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Instructions for Applicants Requesting Medical Use of Lutetium Lu-177 dotatate (LUTATHERA®) and Lutetium Lu-177 vipivotide tetraxetan (PLUVICTO™)

(Rev. 2, June 2023)

Background

On January 26, 2018, the U.S. FDA approved the use of LUTATHERA® ((Lu-177) lutetium dotatate), a radiopharmaceutical for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs). On March 23, 2022, the U.S. FDA approved another Lu-177 radiopharmaceutical, PLUVICTO™ ((Lu-177) lutetium vipivotide tetraxetan) for the treatment of prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer (PSMA-positive mCRPC). On June 1, 2018 and December 8, 2022, the U.S. Nuclear Regulatory Commission (NRC) published corresponding licensing guidance. This supplemental guidance clarifies the applicable subparts of 32 Ill. Adm. Code Part 335 that authorize the use of these radiopharmaceuticals and identifies associated regulatory requirements.

Regulatory Requirements

These radiopharmaceuticals are authorized under IEMA-OHS regulations as follows:

- LUTATHER® and PLUVICTO™ are authorized under 32 Ill. Adm. Code 335.5010 as a beta-producing radiopharmaceutical for parenteral administration.
- Authorized users who are currently qualified via 32 Ill. Adm. Code 335.9050 or 335.9080 may use these radiopharmaceuticals without a license amendment.
- Licensees wishing to add an authorized user of this material shall comply with the provisions of 32 Ill. Adm. Code 335.40, and submit applicable documentation described in 32 Ill. Adm. Code 335.9050 or 335.9080.
- Patients administered these radiopharmaceuticals will generally be eligible for release under 32 Ill. Adm. Code 335.2110, provided an assessment of living conditions is performed and the authorized user is satisfied the patient will comply with provided instructions. The basis for release must be documented by the licensee and records maintained for five (5) years after the release of the individual.

- Consult the package insert for specific precautions to prevent embryo-fetal toxicity. Pregnancy testing, as detailed in 32 Ill. Adm. Code 335.5010(b), is not required for administration of Lu-177.
- The isomer Lu-177m may be present in the patient dose as a production contaminant. Lu-177m emits low-energy photons that are detectable using standard scintillation detectors and Geiger counters, even in low quantities. Lu-177m has a half-life of 160.4 days; therefore, the presence of this isomer would disqualify the residual material for decay-in-storage. The presence of this isomer would necessitate disposal in accordance with 32 Ill. Adm. Code 340.1010(a).
- If Lu-177 radiopharmaceuticals will be administered with an infusion pump, in accordance with 32 Ill. Adm. Code 335.1050(a)(4), only those individuals who are accredited pursuant to 32 Ill. Adm. Code 401.100 or exempt from accreditation by 32 Ill. Adm. Code 401.30, and designated in writing by the licensee, can administer radionuclides to patients. Therefore, only the registered technologist, authorized user, or a physician under the supervision of an authorized user, in accordance with 32 Ill. Adm. Code 335.1050(a), can initiate treatment.

Recommendations

These additional recommendations are provided, but do not constitute regulatory requirements under 32 Ill. Adm. Code Part 335:

- Pregnancy status of patients capable of childbirth should be verified prior to initiating administration.
- Nurses/staff attending the patient should wear smocks, gloves, safety glasses and booties and use standard contamination control techniques.
- Contamination is a concern with patient excreta. Note radioactivity has been reported in the urine for up to 30 days following administration.
- Contamination surveys are generally performed using a Geiger Mueller instrument (pancake probe).
- The dose calibrator should be peaked for Lu-177 for dose assays.
- Some licensees may need to amend their license to add a dedicated room, with a private bathroom, since the infusion/procedure for LUTATHERA® takes many hours and the current facility diagram may not include the area(s) where this material will be used/stored.

Additional Guidance

The following NRC guidance documents may be reviewed for further assistance in establishing procedures for the safe use of Lutetium-177 radiopharmaceuticals.

- NUREG-1556 Volume 9 Appendix U, *RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS ADMINISTERED RADIOACTIVE MATERIALS*
- Regulatory Guide 8.39: *Release of Patients Administered Radioactive Material*
- Lutetium-177 Radiopharmaceuticals (Lutathera® and Pluvicto™), revised December 2022. Available here: https://www.nrc.gov/docs/ML2231/ML22318A150.pdf

Questions regarding this supplemental guidance may be directed to ema.speclic@illinois.gov or you may contact the Radioactive Materials Section at (217) 785-9947.