



January 2, 2019

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U.S. Nuclear Regulatory Commission
Division of Radiation Safety and Safeguards
2100 Renaissance Blvd
King of Prussia, PA 19406

Dear Sir or Madam:

This letter is to clarify issues raised by NRC on December 27, 2018 in evaluating our April 24, 2018 amendment request for clinical use of Th-227.

Waste Disposal

NIH intends to decay-in-storage Th-227 related waste in accordance with Condition 20 of the license by surveying the waste in a low background area with an appropriately sensitive survey instrument with no interposed shielding. If after a suitable waiting time for decay there is still detectable activity that does not appear to be decaying any longer, it will be presumed that Ac-227 (for practical purposes a pure beta emitter) is present in the waste and NIH will treat the waste as radioactive for final disposition.

Facility Surveys

Independent confirmatory surveys for the Th-227 dose preparation location will be performed (typically by the Division of Radiation Safety survey contractor) on a monthly survey frequency. The Th-227 administration location will be the patient's room and surveys will be conducted using a ZnS meter and smears, in accordance with NIH license commitments for I-131 therapy patient room releases, except that allowable contamination limits will be observed as for Ra-226 (NUREG 1556 Vol 9 Rev 2 Appendix R).

Administration Locations

NIH would like to also clarify that the clinical use locations indicated in the license amendment are the most likely locations for Th-227 administration. However, NIH may use another location provided the NIH Radiation Safety Committee has approved this location for Th-227 administration.

If you have any questions or need additional clarification on this amendment request, please contact me at 301-594-1303 or via e-mail at cribaudo@nih.gov.

Catherine A. Ribaud

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cc: Dr. Bradford Wood, Chair, NIH Radiation Safety Committee

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