DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

January 29, 2019

License: 19-00296-10/03001786 J9

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 request an amendment related to the recent approval of Th-227 for clinical use at the NIH.

In the original Th-227 amendment request dated April 24, 2018, the Th-227 administration locations were described as follows:
"The administration [of Targeted Thorium-227 Conjugate (TTC)] will take place in either the I-131 therapy quarantine suite (for convenience) as described in Item 9 of the Broad Scope License application dated July 3, 2012 (ML12194A474) or in a separate facility in the Building 10, B3 level, B wing, which currently conducts radiopharmaceutical administrations under 10 CFR 35.300."

As TTC plans have evolved, the clinical team has decided to utilize any inpatient room on the 5NW patient care unit for Th-227 administrations (i.e., not solely restrict the team to the I-131 therapy quarantine suite or to the Building 10 - B3 facility.) Note that 5NW is the patient care unit referred to in Item 9 of the Broad Scope License application.

Inpatient rooms on the 5NW patient care unit are identical in all respects to the I-131 therapy quarantine rooms (Rooms 5-2672 and 5-2676) described in Item 9 of the Broad Scope License application, except they are not lead-lined. However, a lead-lined room is not necessary for Th-227 therapy patients, and these patients may safely be housed in any 5NW inpatient room.

Therefore, this is to request approval to add any inpatient room on the 5NW patient care unit as an approved location for conducting Th-227 administrations, in addition to the previously-approved locations for this therapy 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. Ribaudo

6/1/68

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

Rec'd. in LAT- 1/29/2019

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee	Date
Department of Health & Human Services ATTN: Catherine Ribaudo, Radiation Safety Officer 21 Wilson Drive Bethesda, MD 20892-6780	January 30, 2019
	License Number(s) 19-00296-10
	Mail Control Number(s) 611168
	Licensing and/or Technical Reviewer or Branch Tara Weidner

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 01/29/2019

The initial processing, which included an administrative review, has been performed.

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link:** http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239