

October 19, 2016

Dr. I

Licensing Assistance Team
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard Suite 100
King of Prussia, Pennsylvania 19406-2713

Subject: License Amendment Request
West Virginia University Hospitals, Inc.
NRC License No. 47-23066-02, Docket 030-20233

REC-102516-0655


This letter is to request an amendment to our radioactive materials license to include Actinium-225 (Lintuzumab-Ac225) for use in the clinical trial study of Lintuzumab-Ac225 treatment of patients with acute myeloid leukemia. We are requesting a maximum possession limit of 20 mCi. Prior to the implementation of use, all policies and procedures associated with the safe utilization of this material shall be reviewed, approved, and ratified by the Radiological Safety Committee.

Lintuzumab-Ac225 doses will be received as a unit dose prepared at an outside radiopharmacy and thus preclude dose manipulation at WVU Hospitals at this time. All patient Ac-225 injections will be conducted in the currently approved area for radioactive materials in the Nuclear Medicine department at Ruby Memorial Hospital.

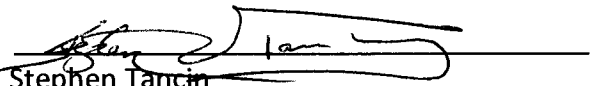
All patient injections of Actinium-225 will be documented with a written directive per 10 CFR Part 35 Subpart E and will be administered by an Authorized User trained in accordance with 10 CFR 35.390.

If any additional information is needed please contact Nasser Razmianfar, RSO at 304-293-3413.

Sincerely,



Nasser Razmianfar
Director and Radiation Safety Officer



Stephen Tancin
Vice President, Ancillary and Support Services

592217
NMCS/RONI MATERIALC-002



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

West Virginia University Hospitals, Inc.
ATTN: Stephen L. Tancin, Vice President
P. O. Box 9006, Medical Center
Morgantown, WV 26506-9006

Date

October 31, 2016

License Number(s)

47-23066-02

Mail Control Number(s)

592217

Licensing and/or Technical Reviewer or Branch

Medical Branch (Branch 1)

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: October 19, 2016

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
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Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
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(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239