UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

June 10, 2024

Karl W. Fischer, CHP
Director and Radiation Safety Officer
The Regents of the University of Michigan
Radiation Safety Service: Occupational Safety & Environmental Health
1239 Kipke Dr.
Ann Arbor, MI 48109-1010

SUBJECT: ADDITIONAL INFORMATION REQUEST, UNIVERSITY OF MICHIGAN, NRC LICENSE NO. 21-00215-04, MAIL CONTROL NO. 640572

Dear Karl Fischer:

This refers to The Regents of the University of Michigan - Radiation Safety Service: Occupational Safety & Environmental Health's (your) April 30, 2024, request, for an amendment to U.S. Nuclear Regulatory Commission (NRC) Radioactive Materials license, NRC License No. 21-00215-04, requesting to update your iridium-192, as permitted under Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.600, in an HDR remote afterloader unit, authorization, to a new model device and to an increased time-of-medical use possession limit.

We have reviewed your request and have noted that additional information is needed to complete our review. If you are unable to provide the requested information within the next 14 days (on or before June 24, 2024), please contact me at 630-829-9892 or via electronic mail at sara.forster@nrc.gov.

Please provide the following information to complete our review of your application:

1. The referenced letter indicated that the new medical use activity limit should be increased to 15 curies. However, no shielding evaluation was included in the application. NUREG 1556, Vol. 9, rev. 3, "Consolidated Guidance," Section 8.9.1, "Facility Diagrams," p. 8-50, indicates that shielding calculations for HDR Remote Afterloaders should be provided. The submission should "Include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used." No such evaluation was included with the request.

   NUREG 1556, Vol. 9, rev. 3, p. 8-50, further indicates that, "For ... sealed-source therapies, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003. For calculations of the maximum exposure in any given hour, an occupancy factor will not be used."

A shielding evaluation is needed to determine whether the facilities are adequate.

Please provide a current diagram of the HDR suite, showing safety features, thicknesses of walls, surrounding areas, and occupancy factors, etc. Please provide a shielding evaluation for the HDR suite demonstrating that the shielding is adequate for a 15-curie source.

2. The referenced letter indicated that the "administrative and operational elements of the HDR treatment program are unchanged," in spite of the upgrade of the HDR device to the BRAVOS. Please note that 10 CFR 35.12(c)(2) requires that spot check procedures required by 10 CFR 35.643 be submitted with the request for the HDR. No updates to the spot check procedures were submitted with the request to include the BRAVOS HDR unit.

   Please either provide a copy of your current HDR spot check procedure or confirm that previously submitted HDR spot check procedures are current.

Please provide your response as a signed and dated letter. For quickest processing, please submit the response electronically as a pdf file attached to an email. Thank you for your cooperation.

Sincerely,

SARA FORSTER

Digitally signed by SARA FORSTER
Date: 2024.06.10 09:41:18 -05'00'

Sara A. Forster, MS, Health Physicist
Materials Licensing Branch
Division of Radiological Safety and Security
Region III

NRC License No. 21-00215-04
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