OSEH
Occupational Safety &
Environmental Health

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November 22, 2011

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

RE: **Response to an Apparent Violation in Inspection Report No. 03001988/2011001(DNMS); EA-11-228**
University of Michigan
(Materials License No. 21-00215-04)

Dear Ms. Bloomer:

On March 10, 2011 the University of Michigan (U-M) reported what was determined to be a medical event resulting from the administration of Yttrium-90 TheraSpheres to a patient on March 9, 2011. In accordance with NRC regulations, the U-M submitted a written report dated March 21, 2011 that described the incident, related events, root causes identified by the licensee's Radiation Oncology group, and the corrective actions put into effect by Radiation Oncology to prevent a recurrence.

As a result of the notification, the NRC conducted a reactive inspection on March 15-16, 2011 with on-going review through October 6, 2011. The NRC prepared and submitted to the U-M a Reactive Inspection Report dated October 28, 2011 [No. 03001988/201101(DNMS)] detailing its findings and conclusions. As part of its preliminary findings, the NRC identified an apparent violation of the provisions of 10 CFR 35.41(a) and (b)(2). Additionally, the NRC noted in its report that it accepts the licensee's assessment of root causes as described in the licensee's report of March 21, 2011. Finally, the NRC concludes the corrective actions adopted by the licensee's Department of Radiation Oncology will sufficiently address and correct the root causes of the reported medical event.

The U-M has been offered an opportunity to request a Predecisional Enforcement Conference (PEC) or to submit written comments regarding the inspection report for purposes of clarifying any factual matters or errors as described in the NRC Reactive Inspection Report.

The U-M will decline requesting a PEC. In lieu of a PEC, we have identified some factual matters we believe bear clarifying or correcting, but which can be done so through a written response. We respectfully submit these comments for inclusion into the record:

1.0 Report Details (Section 2.2 / Page 5 / Paragraph 3):

The report states: "In discussions with the medical physicist and authorized user, it was clarified that the interventional radiologist was the individual who developed the treatment plan. The treatment plan included the size of the treatment location, which is necessary to determine the correct activity to the patient as documented in the written directive. However, the interventional radiologist did not review the written directive nor did the medical physicist or authorized user review the treatment plan prior to administration which would have identified the incorrect target volume."

Licensee Response:

The Department of Radiation Oncology would like to correctly describe the division of duties among Radiation Oncology and Radiology personnel and clarify the activities that led to the event.

1.1 Division of Duties: The interventional radiologist determined the treatment site, volume, and lung shunt fraction. The authorized user determined the patient's prescription dose based on the information calculated by the medical physicist and which was to be verified by the authorized user.

1.2 Activities Leading to Event: The medical physicist and authorized user reviewed the worksheet from interventional radiology but did not identify the correct volume size for treatment. We believe that a root cause of this is that a form from a study on December 10, 2010 was used where the additional target site and volume were listed at the bottom of the page with a title of "Liver Volumes" whereas the initial target site was listed on top of that form as "Target Site". As a result of the medical event, the forms and procedures were immediately revised so that each target site has its own interventional radiology worksheet for use in calculating the patient's treatment plan.

2.0 Report Details (Section 2.2 / Page 5 / First Paragraph / Last Sentence)

The sentence currently reads: 'The medical physicist explained to the inspector that this error was *also* the result of using documentation prepared for the treatment in December 5, 2010.'

Correction: "The medical physicist explained to the inspector that this error was the result of using documentation prepared for the treatment on December 5, 2010." (Remove the word 'also' and replace 'in' with 'on' December 5, 2010)

3.0 Partial List of Persons Contacted (Page 9)

3.1 Ian Stienman—Associate Director / Fire Marshall should read ***Ian Steinman***—*Associate Director / Fire Marshall*

3.2 Mark Discoll- Radiation Safety Officer should read ***Mark Driscoll*** - *Radiation Safety Officer / OSEH*

3.3 Dennin Palmieni should read ***Dennis Palmieri,*** *Radiation Safety Service / OSEH*

Thank you for your time and consideration in this matter. Please do not hesitate to contact me [(734) 647-2251] or Senior Health Physicist Dennis Palmieri [(734)764-9182] at Radiation Safety Service / OSEH should you have any questions or comments regarding this U-M response to Inspection Report No. 03001988 / 201101 (DNMS) dated October 28, 2011.

Sincerely,

S K Benedict

Stephen Benedict, Director
Department of Occupational safety & Environmental Health

cc: Mark Driscoll, Radiation Safety Officer, Radiation Safety Service / OSEH
Mary Feng, M.D., Authorized User, Assistant Professor, Radiation Oncology
Jean Moran, Ph.D., Associate Division Director, Associate Professor, Radiation Oncology
Ruthann Nichols, Ph.D., Associate Professor – Biological Chemistry, Chair - Radiation Policy Committee
Joann Prisciandaro, Ph.D., Medical Physics Residency Director, Clinical Assistant Professor, Radiation Oncology