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March 22, 2011

U.S. Nuclear Regulatory Commission, Region III
Materials Inspection Branch
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532- 4352

SUBJECT: Medical Event
University of Michigan Hospitals and Health Centers (March 9, 2011)
NRC License No. 21-00215-04 (Docket No. 030-01988)

Materials Inspection:

The University of Michigan is submitting the attached written report regarding a Medical Event that occurred at the University of Michigan Hospitals and Health Centers on March 9, 2011. The medical event was initially reported by phone to the NRC Operations Center on March 10th and the Operations Center issued Event Report No. 46665.

This report is submitted in accordance with the provisions of 10 CFR 35.3045(d). It describes the event, the determined causes, the corrective actions that have been implemented, and other requirements outlined in 10 CFR 35.3045(d)(1).

Thank you for your time and consideration with respect to this report. Please do not hesitate to contact Senior Health Physicist Dennis Palmieri or me at Radiation Safety Service / OSEH [(734) 764-6200] should you have any questions or comments regarding this report or the event.

Sincerely,

Mark L. Driscoll
Director / Radiation Safety Officer
Radiation Safety Service / OSEH

cc: J. Prisciandaro
J. Moran
M. Feng
Files

/enc

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Radiation Safety Service
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March 21, 2011

Report on Medical Event of March 9, 2011

In accordance with the notification provisions of Title 10 Code of Federal Regulations Part 35.3045(d), The University of Michigan is submitting a written report describing a medical event occurring on March 9, 2011 at the U-M Hospitals and Health System and reported to the NRC Operations Center on March 10, 2011 by Mark Driscoll, Radiation Safety Officer and Director, University of Michigan OSEH-Radiation Safety Service. This report summarizes the events prompting notification, assessed causes, and proposed remedial actions.

Licensee:	The Board of Regents of the University of Michigan
License Number:	21-00215-04
NRC Operations Center Event Report No.:	46665
Prescribing Physician:	Mary Feng, M.D., Assistant Professor of Radiation Oncology, Department of Radiation Oncology
Interventional Radiologist:	Paula Novelli, M.D., Assistant Professor of Radiology Division of Interventional Radiology--Department of Radiology
Authorized Medical Physicist:	Joann Prisciandaro, Ph.D., Assistant Professor of Radiation Oncology Department of Radiation Oncology

Summary of Event

Isotope:	Y-90
Form:	TheraSpheres

On March 9, 2011, physicians, including the prescribing physician, performed an infusion of Y-90 TheraSpheres, as a brachytherapy treatment, into the left lateral lobe of an adult male patient. The patient suffers from non-resectable hepatocellular carcinoma. This was the second of two TheraSphere treatments. The first treatment was for an infusion into the right lobe and left medial segments of the liver. That was performed on December 15, 2010 and preceded without incident. The second treatment was delivered, as intended, to the left lateral lobe. However, due to a misunderstanding arising from a lack of sufficiently specific communications between the prescribing physician and the medical physicist, the wrong liver segment volume was used to calculate the activity needed to deliver the dose to the left lateral lobe. The intended radiation dose was 74.4 Gy. The actual dose delivered was estimated to be 159.4 Gy based on post-infusion dosimetry. The final dose was determined using the most recent MRI image of the liver and assessing the current volume of the left lateral lobe to be 637 cc.

Description of Event

Background

The prescribing physician in consult with other physicians, including the interventional radiologist, made a medical determination that the patient should be treated with Y-90 TheraSpheres. This was done in two separate treatments. The first treatment was to the right lobe and left medial segment of the liver. The second treatment was to the left lateral lobe of the liver. It should be noted that the left lateral lobe was the site intended to be treated by both the interventional radiologist and the prescribing physician although the written directive prepared by the medical physicist for the second treatment erroneously described the treatment site as "medial segment".

Preparatory Evaluation of November 29, 2010 ("IR Worksheet")

The interventional radiologist performed a preparatory evaluation of the liver volumes and lung shunt fraction on November 29, 2010. She prepared a worksheet ("IR Worksheet") and forwarded it to the medical physicist. Near the top of the form, the worksheet identified only the treatment site for the first treatment scheduled for December 15, 2010. It described the treatment site as the "right lobe and left medial segment" and provided a corresponding volume of the two segments combined as 1333.64 cc. At the bottom of the form, the radiologist listed the volume for the left lateral lobe as 411.12 cc along with a total liver volume of 1744.76 cc. The form did not specifically identify the left lateral lobe as a second treatment site.

In addition to liver volumes, the worksheet includes the lung shunt fraction determined through a Tc-99m MAA angiogram. The shunt fraction for this patient was well within specifications and was not a factor in the medical event.

Once the Radiation Oncology medical physicist receives the IR Worksheet, the medical physicist uses the IR worksheet to calculate the Y-90 activity that is to be administered to the patient in order to deliver the prescribed radiation dose. That information is then entered into a draft of the written directive and submitted to the prescribing physician and another medical physicist for confirmation and approval. All of this is in accordance with the written procedures associated with this type of administration.

First Treatment

The first treatment was conducted on December 15, 2010 and preceded without incident.

Second Treatment

On February 22, 2011, the prescribing physician notified the medical physicist that the second treatment was scheduled for March 9, 2011. The physician did so, informally, by an email to the medical physicist that didn't clearly specify the desired treatment site in a manner consistent with the terminology used in the IR worksheet. Specifically, the doctor advised the physicist:

> "...We are planning to treat his left side on 3/9. Can you please run the calcs? We will use the numbers from his angio on 11/29/10."

The Authorized User intended "left side" to mean the left lateral lobe of the liver.

Radiation Oncology did not have a formal, written document that a prescribing physician would use to request a medical physicist prepare calculations and a draft written directive. The IR worksheet is prepared principally by the interventional radiologist strictly as a worksheet to provide diagnostic, pathological and anatomical data to the physicist relevant to the treatment site desired by the prescribing physician as described on the worksheet. However, the radiation oncologist does not make any entries onto the form and it is not signed by either physician.

The February 22, 2011 e-mail was the principal written communication between the prescribing physician and the medical physicist. In this instance, the email was brief and without details. It did not clearly specify the treatment site as the left lateral lobe. In addition, it directed the physicist to use the original IR Worksheet from November 29, 2010 that was prepared by the radiologist for the treatment on December 15, 2010. That worksheet doesn't identify the left lateral lobe as a treatment site, instead referring to the "right lobe and left medial segment".

The medical physicist listed the treatment site on the draft written directive as "medial segment". The physicist also listed the corresponding volume from the IR Worksheet of 1333.64 cc which was actually the combined volume for the right lobe and the left medial segment. However, the volume for left lateral lobe—as measured on November 29, 2010 was only 411.12 cc.

The volume was used in an Excel spreadsheet to determine the Y-90 activity needed to deliver the prescribed dose of 74.4 Gy to the liver segment being treated. The medical physicist used a volume of 1333.64 cc rather than the left lateral lobe volume of 411.12 cc and calculated a dosage of 2.24 GBq (60.5 mCi) for the Y-90 treatment. The medical physicist included this dosage on the draft written directive which she then submitted to the prescribing physician and a second medical physicist for review and approval. This was done by an e-mail in accordance with written procedures. The procedures instruct the physicist preparing the written directive to "...E-mail the AU and another AMP and ask them to check the calculation."

Both the prescribing physician and the second medical physicist failed to notice the discrepancies in treatment site and volume. Neither can recall why that may have happened with any certainty. The physician approved the written directive as originally prepared.

Using the correct volume of 411.12 cc for the left lateral lobe as logged on the IR Worksheet instead of the 1333.64 cc, the dosage would have been about one-third of that calculated.

NOTE: Subsequent MRI data indicated that the left lateral lobe volume was 637 cc at the time of the treatment on March 9, 2011. The Y-90 activity of 60.5 mCi infused, therefore, resulted in a radiation dose estimated at 159.4 Gy. This was approximately 100% higher than the prescribed dose of 74.4 Gy.

Determination of No Significant Medical Effect

Both the radiologist and the radiation oncologist have assessed the patient since the date of the event. Both find the patient to be doing well and responding well to the treatment. The radiation oncologist has made a medical determination that the higher radiation dose is not expected to cause permanent medical damage to the patient's liver nor further loss of function from that which existed prior to treatment.

Notification of Patient

The patient was promptly notified on March 9, 2011 of the event (same day of occurrence) and was also advised of his right to a written description of the event as required by 10 CFR 35.3045(e).

In addition, the referring physician was also notified on March 10, 2011. A copy of this report will be provided to the referring physician in accordance with 10 CFR 35.3045(g)(2).

Causes of the Event

1) Normally, most patients only receive one treatment and a single IR Worksheet is prepared and submitted to the medical physicist by the interventional radiologist after consultation with the radiation oncologist. Neither the radiologist nor the radiation oncologist signs or dates the form.

2) The history of bi-lobar or other multiple treatments at the UM has been sparse prior to this instance. Even in those few instances of multiple treatments, the radiologist normally conducted separate preparatory evaluations prior to each treatment preparing a new and separate IR worksheet each time for use by a medical physicist.

   This patient lived a great distance from the hospital and was substantially ill. Both the radiologist and the radiation oncologist deemed it medically advisable to conduct a single preparatory evaluation. As such, the medical physicist had only the single IR worksheet for use with both treatments but the worksheet only identified the treatment site for the first of the two treatments performed on December 15, 2010.

3) The prescribing physician and medical physicist communicated informally and without sufficient detail regarding the site and parameters relevant to the intended treatment. An e-mail vaguely referenced treatment to the "left side" of the liver and instructed the medical physicist to use the "numbers" from the same IR worksheet used with the first infusion of December 15, 2010. Near the top of that worksheet the treatment site is described as the "right lobe and *left* medial segment" (Note: the form did include volume information for the left lateral lobe but only near the bottom of the form).

   The terminology used in the e-mail to describe the intended treatment site was inconsistent with that used in the IR worksheet and not detailed enough to distinguish the intended target clearly. The oncologist's intent was that the medical physicist should prepare a written directive for infusion into the left lateral lobe. But, the e-mail did not distinguish "left medial segment" from "left lateral lobe".

4) There was a failure on the part of the prescribing physician and the second medical physicist to comprehensively review the draft written directive in its entirety. Existing procedures did not require either to complete a formal, documented review checklist that would require either or both to confirm all the relevant parameters in the draft directive. Reviews were informal and evidenced only by signature on the written directive.

Corrective Actions

The Y-90 TheraSpheres written procedures have been modified to introduce new, more robust administrative controls. These controls should eliminate or reduce reliance on informal communications, add greater consistency in terminology and routine, and require documented accountability from those preparing and reviewing necessary forms and directives:

1) Radiation Oncology has modified the Interventional Radiology ("IR") worksheet that must be completed by the radiologist to clearly designate the necessary diagnostic, pathological, and anatomical information needed to prepare for such a treatment.

The radiologist must sign the form. These changes establish a consistent terminology for identifying the appropriate segment volume. For purposes of measuring volume, liver segments are clearly designated on the form as right lobe, left lobe and total liver volume. This consistency will be carried over into a modified written directive.

2) The revised IR worksheet now also includes a separate section which the radiation oncologist must also complete and sign. The radiation oncologist must specify, in writing, the specific treatment site and the exact segment volume to use. In addition, the oncologist will include the date and time of the planned infusion. A separate worksheet must be completed and submitted to the medical physicist for each infusion treatment planned—even if the medical data supplied by the radiologist will remain unchanged for purposes of preparing a draft written directive.

3) The written directive form for Y-90 TheraSpheres has been modified to require entry of the specific treatment site in terms of right lobe, left lobe or whole liver as is consistent with the newly modified IR worksheet.

4) The prescribing physician and a second medical physicist will continue to review and approve the written directive. But, both will be required to complete and sign a separate TheraSphere Infusion Checklist when reviewing the draft directive. This checklist requires both to confirm that the treatment site and the treatment volume identified in the written directive are consistent with the information supplied in the IR worksheet.

5) An Operating Room checklist that, per existing procedure, is completed prior to and during the surgical infusion procedure has been modified to include confirmation immediately before the procedure that the treatment infusion site and associated volume described in the written directive are correct.

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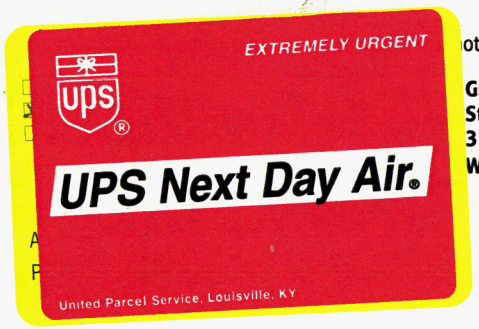

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