



INDIANA UNIVERSITY

OFFICE OF THE EXECUTIVE VICE PRESIDENT
FOR UNIVERSITY ACADEMIC AFFAIRS
University Environmental Health and Safety

IUPUI/IUMC Radiation Safety Office

23 April 2021

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

U.S. Nuclear Regulatory Commission – Region III
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03001609

Notification of Overexposure under 10 CFR 20.2203(a)(2)(i), NRC License No. 13-02752-03

To Whom it May Concern:

This letter is a notification of an exposure in excess of occupational dose limits, as required under 10 CFR 20.2203(a)(2)(i).

The NRC conducted an inspection of our facility on October 19th-20th, 2020, in response to a reported medical event (notification no. 54946). As part of this ongoing inspection, it was discovered that a physician performing Y-90 radioembolization procedures, in addition to interventional radiology procedures utilizing fluoroscopy, had not been wearing their dosimeter. The inspector requested a dose reconstruction to be performed for the years 2012-2020, which resulted in the discovery of these overexposures, as documented in our response dated 22 April 2021.

1) Estimation of Dose (20.2203(b)(1)(i)):

2012 TEDE of 5.132 rem
2013 TEDE of 7.082 rem

Other doses (LDE, SDE_WB, SDE_ME) were not exceeded for these dates. Detailed methods used for this dose reconstruction were submitted to the NRC in response to the ongoing inspection on 22 April 2021.

2) Levels of Radiation/Radioactive Material (20.2203(b)(1)(ii)):

The physician receiving the overexposures was exposed to radiation during Y-90 radioembolization procedures and scattered x-radiation from interventional fluoroscopy use. Historical data is not available for the number of Y-90 procedures performed in 2012 or 2013, but an average of 20 per year was assumed based on data from other years (range of 8-23, median of 15). Annual contribution to TEDE from Y-90 procedures was calculated to be less than 20 mrem. The remainder of the received dose was from intermittent use of fluoroscopy, with estimated exposure rates in the 0.23-0.44 mR/min range.

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3) Cause of Elevated Exposures (20.2203(b)(1)(iii)):

The reason for this individual's overexposure is likely due to a) clinical case load, and b) assumptions utilized in dose reconstruction.

- a) The physician in question performs many complicated interventional procedures. When compared to a peer interventional radiologist who also had dose reconstructions performed, this physician had recorded fluoroscopy times (amount of time x-ray beam was on) around 10 times as high as their peer, on average. In addition, the number of complex procedures performed was considerably higher.
- b) As the physician was not wearing their issued dosimeter, which resulted in these dose reconstruction efforts, several assumptions were made to ensure conservative estimations were being performed. One key assumption was that the physician did not leave the room during continuous fluoroscopy use modes, such as cineradiography and digital subtraction angiography modes. Typically, physicians leave the procedure room during these exposures, but will occasionally stay in the room due to patient care issues. Dose reconstruction efforts assumed that the physician remained within the room for all exposures.

4) Corrective Actions (20.2203(b)(1)(iv)):

Several corrective action steps have been implemented to ensure against recurrence. The root cause of these overexposures was lack of proper dosimeter wear by the physician. As dosimeters are exchanged monthly, trends towards overexposures would normally be identified prior to reaching limits. As this was noted in October 2020 during the inspection, corrective actions have already begun.

- a) Update to institutional ALARA program. Previously, our institutional ALARA program only "flagged" or reviewed exposures above certain thresholds. Changes have been made where unreturned/unused dosimeters, especially in groups where significant exposure is expected, are "flagged" and reviewed as well.
- b) The Director of Interventional Oncology and Chief of Vascular and Interventional Radiology, who is also a Y-90 radioembolization AU and supervisor of all physicians performing Y-90 radioembolizations, has implemented a mandatory annual compliance acknowledgement for these physicians. This document outlines proper dosimetry wear and return procedures, and institutes consequences for non-compliance in dosimeter wear. Briefly, 1 instance of noncompliance results in a warning letter. Two instances result in restriction from Y-90 procedures for 3 months and completion of a radiation safety review course. Three instances result in total removal from Y-90 use. A detailed copy of this program has been submitted as part of the ongoing review.
- c) The RSO spoke to the Hospital System-wide Radiology Leadership Council on 3 December 2020 to emphasize importance of proper dosimeter wear and gain leadership support and "policing" assistance (e.g. checking physicians for appropriate badge wear) at departmental levels.

In addition to the above information, the physician receiving the overexposure was notified of their overexposure on 23 April 2021 via email, in accordance with 10 CFR 20.2205. A copy of this email is appended to this letter. An additional sheet is appended, containing private personal information required by 10 CFR 20.2203(b)(2).

Sincerely,



T. Michael Martin, PhD, DABHP

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