Ascension
Borgess Hospital

David Curtis, Director
Division of Radiological Safety and Security
United States
Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4382

SUBJECT: Response to: NRC ROUTINE INSPECTION REPORT NO. 03002115/2023001 (DRSS) – ASCENSION BORGESS HOSPITAL

Dear David Curtis:

Thank you for working with us on the review and proposed resolution to the following apparent NRC violations. Ascension Borgess takes these very seriously and feels confident that you will find the documented actions and responses appropriate and secure.

Violation One:

Five administrations of Y-90 TheraSpheres occurred for which a written directive had been prepared but was not dated and signed by an authorized user (AU) prior to the administration. In each case the AU dated and signed the written directive after the administration. The administrations of concern occurred on August 5, 2021; September 10, 2021; October 13, 2021; November 4, 2021; and January 20, 2022.

Licensee Actions:

The lack of timely signatures by the AU were self-discovered by the Borgess RSO, during a periodic program review on January 4, 2023. These were determined to have been facilitated, in part, by inadequate formal processes. Process changes were immediately made requiring: (1) the AU is to date-and-sign the Written Directive prior to Nuclear Medicine being able to order the Y-90 dose(s); (2) the RSO to verify the Written Directive has been signed when he/she performs a verification of the dosimetry calculation prior to the administration.

Subsequent records reveal full compliance, as evidenced by no further violations having occurred following the internal program review and discovery on, 4 January 2023.

Violation Two:

Immediately upon discovery of a sealed-source lost in transit by a common carrier, the Nuclear Medicine staff contacted the NRC by phone, but failed to submit a written report within the following 30 days. This is a violation of NRC 10 CFR 20.2201(b).

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Licensee Actions:

As corrective steps, the technical staff was educated by the RSO in the NRC reporting requirements to both call the NRC and send a written report within 30 days if a source is lost in transit. To avoid further violations: (1) upon becoming aware of the loss, the Nuclear Medicine staff is to immediately call the NRC to report the incident; (2) the Nuclear staff is to immediately notify the Borgess RSO and Radiology Administrator to make them aware of the missing source and of the completed call to the NRC; (3) The RSO and Administrator will jointly coordinate the written notification to the NRC; (3) the RSO and Administrator will be responsible for providing a written notification to the NRC within the required 30-day notification period.

As a corrective action for the apparent existing violation, the licensee submitted the written report to the NRC on, February 24, 2022.

Please feel free to contact me directly if you feel the need for further discussions or follow-up.

Sincerely,

James E. Stopford, Regional Director
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cc: Paul Jursinic, Ph.D., RSO
State of Michigan