



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

April 1, 2024

EA-23-109  
NMED 210495 (closed)

Jim Stopford  
Regional Director of Radiology  
Ascension Borgess Hospital  
1521 Gull Rd.  
Kalamazoo, MI 49048

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT  
NO. 03002115/2023001 (DRSS) - ASCENSION BORGESS HOSPITAL

Dear Jim Stopford:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on July 19 and 20, 2023, at your Kalamazoo and Battle Creek, Michigan facilities with continued in-office review through November 16, 2023. The purpose of the inspection was to review activities performed under your NRC license to ensure activities were being performed in accordance with NRC requirements. During the inspection, two apparent violations of NRC requirements were identified. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you during an exit meeting on November 16, 2023. Inspection Report No. 03002115/2023001 (DRSS); was issued on December 7, 2023, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML23272A189. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter received by the NRC on January 16, 2024 (ML24067A291), and an email dated March 7, 2024, from your Director of Radiology & Cardiology Services (ML24067A293), you provided responses to the apparent violations.

Based on the information developed during the inspection and the information that you provided in your responses to the inspection report received on January 16, 2024, and March 7, 2024, the NRC has determined that two violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

Violation A involved the failure to have an authorized user date and sign a written directive before five administrations of Y-90 microspheres, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35.40(a). The failure to develop a written directive appropriate for the circumstances is a significant safety concern in that the failure to develop appropriate written directives could result in an incorrect dose being delivered to the patient, and result in a medical

event. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$9000 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. Corrective actions included: (1) requiring the authorized user to date and sign the written directive prior to nuclear medicine staff being able to order the yttrium-90 doses; (2) the radiation safety officer verifying the written directive has been signed when performing a verification of the dosimetry calculation prior to the administration; (3) revising procedures to include the process changes listed above; (4) training all involved staff, including nuclear medicine staff, on revised procedures and process changes; (5) the radiation safety officer being the final check to ensure the written directive is signed prior to allowing the dose to be administered, and (6) the lead Nuclear Medicine Technologist will be attending the procedures and also overseeing the process. Based on the above, *Corrective Action* credit is warranted.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>).

The NRC has also determined that a Severity Level IV violation of NRC requirements occurred (Violation B). This violation involved the failure to submit a written report within 30 days of making a telephone report identifying that a sealed source was lost in transit as required by 10 CFR 20.2201(b). This violation was also evaluated in accordance with the NRC Enforcement Policy. The violation is cited in the enclosed Notice and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because it was identified by the inspector.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03002115/2023001 (DRSS), your letter received on January 16, 2024, and an email dated March 7, 2024. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if any, will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must

specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

If you have any questions concerning this matter, please contact Diana Betancourt-Roldan of my staff at 630-810-4373.

Sincerely,



Signed by Giessner, Jack  
on 04/01/24

John B. Giessner  
Regional Administrator

Docket No. 030-02115  
License No. 21-12275-02

Enclosure: Notice of Violation

cc w/encl: Paul Jursinic, Ph.D., RSO  
State of Michigan

Letter to J. Stopford from J. Giessner dated April 1, 2024.

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT  
NO. 03002115/2023001 (DRSS) - ASCENSION BORGESS HOSPITAL

DISTRIBUTION w/encl:

RidsSecyMailCenter  
OCADistribution  
Ray Furstenau  
David Pelton  
June Cai  
Juan Peralta  
Carmen Rivera Diaz  
Jack Giessner  
Mohammed Shuaibi  
Raymond Lorson  
Laura Dudes  
John Monninger  
Lorraine Baer  
John Lubinski  
Robert Lewis  
Kevin Williams  
Michele Burgess  
Raymond McKinley  
Mark Kowal

Jeremy Groom  
Diana Betancourt-Roldan  
Shelbie Lewman  
Holly Harrington  
Thomas Ashley  
Meghan Blair  
Jeffrey Hamman  
David Curtis  
Karla Stoedter  
Rhex Edwards  
MIB Inspectors  
Allan Barker  
Harral Logaras  
Darren Piccirillo  
Viktoria Mitlyng  
Prema Chandrathil  
Kenneth Lambert  
Geoffrey Edwards  
Sarah Bakhsh  
RidsOemailCenter Resource

ADAMS Accession Number: ML24074A359

Publicly Available     Non-Publicly Available     Sensitive     Non-Sensitive

OFFICE	RIII-EICS		RIII-DRSS		RIII-DRSS		NMSS	
NAME	KLambert:bw		REdwards		DCurtis		MBurgess	
DATE	3/14/2024		3/18/2024		3/19/2024		3/21/2024	
OFFICE	OE		RIII-EICS		RIII-ORA			
NAME	JPeralta		GEwards for DBetancourt-Roldan		JGiessner			
DATE	3/28/2024		3/28/2024		4/1/2024			

**OFFICIAL RECORD COPY**

## NOTICE OF VIOLATION

Ascension Borgess Hospital  
Kalamazoo, Michigan

Docket No. 030-02115  
License No. 21-12275-02  
EA-23-109

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on July 19 and 20, 2023, with continued in-office review through November 16, 2023, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Title 10 of the *Code of Federal Regulations* (10 CFR) 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material.

Contrary to the above, between August 5, 2021, and January 20, 2022, the licensee failed to prepare written directives that were dated and signed by an authorized user before administration of any therapeutic dose of radiation from byproduct material. Specifically, five written directives prescribed yttrium-90 microspheres to deliver a therapeutic dose of radiation were dated and signed by an authorized user after the administration rather than before administration.

This is a Severity Level III violation (Enforcement Policy Section 6.3 c.2).

- B. Title 10 CFR 20.2201(b) requires, in part, that each licensee required to make a report under paragraph (a) of 10 CFR 20.2201 shall, within 30 days after making the telephone report make a written report.

Contrary to the above, between November 18, 2021, and February 24, 2022, the licensee failed to make a written report within 30 days after making a telephone report. Specifically, the licensee made a telephone report as required by paragraph (a) of 10 CFR 20.2201 on November 18, 2021, but failed make the written report until February 24, 2022, a period greater than 30 days after making the telephone report.

This is a Severity Level IV violation (Enforcement Policy Section 6.9 d.2).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03002115/2023001 (DRSS), the licensee's letter received by the NRC on January 16, 2024, and the licensee's email dated March 7, 2024. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, (EA-23-109)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

Enclosure

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 1<sup>st</sup> day of April 2024.