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

January 26, 2023

EN 56139
NMED No. 220433 (Closed)

Alan Jackson
RSO
Henry Ford Hospital
Radiation Safety Office K-3
2799 W. Grand Blvd.
Detroit, MI 48202

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002043/2022001(DRSS) AND NOTICE OF VIOLATION – HENRY FORD HOSPITAL

Dear Alan Jackson:

On October 18, 2022 through January 3, 2023, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your Grand Blvd. Detroit, Michigan location, with continued in-office review through January 3, 2023. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of medical event number (EN) 56139. Mr. Luis Nieves of my staff conducted a final exit meeting by telephone with you on January 3, 2023 to discuss the inspection findings. This letter presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation concerned the licensee's failure to provide high confidence in their procedures for yttrium-90 (Y-90) microspheres administrations, as required by Title 10 of the *Code of Federal Regulations* (CFR) Part 35.41. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation because the violation was revealed through an event.

The inspector determined that the root cause of the violation was human error. As corrective actions to restore compliance and to address the potential for recurrence, treatment protocol will be changed in three ways. First, the treating interventional radiologist will now specify the intended treatment in writing. Second, the treatment plan review procedure will add a formal review of the written directive by the treating interventional radiologist physician. And third, the

treatment quality control procedure will include a verbal verification of the treatment site by the treating interventional radiologist prior to administering the dose.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and to address recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter and in the attached inspection report. Therefore, you are not required to respond to this letter unless the description herein 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 the NRC's "Rules of Practice," in 10 CFR 2.390, a copy of this letter, its enclosure, and any response you provide will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Mr. Nieves of my staff if you have any questions regarding this inspection. Mr. Nieves can be reached at 630-829-9571.

Sincerely,

Signed by Edwards, Rhex
on 01/26/23

Rhex Edwards, Chief
Materials Inspection Branch
Division of Radiological Safety and Security

Docket No. 030-02043
License No. 21-04109-16

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03002043/2022001(DRSS)

cc w/encl: State of Michigan

Letter to A. Jackson from R. Edwards, dated January 26, 2023.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002043/2022001(DRSS) AND NOTICE OF VIOLATION – HENRY FORD HOSPITAL

DISTRIBUTION w/encl:
Jack Giessner
Julio Lara
David Curtis
Tamara Bloomer
Jared Heck
Diana Betancourt-Roldan
Kenneth Lambert
Sarah Bakhsh
MIB Inspectors

ML23025A014

OFFICE	RIII-DRSS		RIII-DRSS					
NAME	LNieves		REdwards					
DATE	1/25/2023		1/26/2023					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Henry Ford Hospital
Detroit, MI

License No. 21-04109-16
Docket No. 030-02043

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 18, 2022 with continued in-office review through January 3, 2023, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the Code of Federal Regulations (10 CFR) Part 35.41(a) states, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Title 10 CFR 35.41(b) states, in part, that at a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material, including verifying that the administration is in accordance with the treatment plan and the written directive.
>
> Contrary to the above, on October 3, 2022, the licensee failed to provide high confidence in their procedure that each administration is in accordance with the treatment plan and written directive. Specifically, the written directive contained an incorrect treatment location compared to the treatment plan that was not resolved prior to the administration.
>
> This is a Severity Level IV violation (Section 6.3.d.1).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket and in the attached inspection report. 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, IR 03002043/2022001(DRSS)" 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, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from 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, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-02043
License No.	21-04109-16
Report No.	03002043/2022001(DRSS)
NMED No.	220433
Licensee:	Henry Ford Hospital
Facility:	Radiation Safety Office K-3 2799 W. Grand Blvd. Detroit, MI 48202
Inspection Dates:	10/18/2022 – 1/3/2023
Exit Meeting Date:	January 3, 2023
Inspector:	Luis Nieves, Health Physicist
Approved By:	Rhex Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Security

EXECUTIVE SUMMARY

Name of licensee
NRC Inspection Report 03002043/2022001(DRSS)

This was an announced, reactive inspection, performed in response to a medical event reported to the U.S. Nuclear Regulatory Commission (NRC) on October 4, 2022. Henry Ford Hospital (licensee) operates several medical facilities in the Detroit, Michigan area; this event occurred at the main hospital, located at 2799 West Grand Boulevard. The medical event, which occurred on October 3, 2022, concerned an yttrium-90 (Y-90) microspheres treatment in which the licensee wrote the wrong treatment site on the signed written directive. This was not discovered until after the procedure was done; however, there was no harm to the patient since the actual procedure treated the intended treatment site by the referring physician and was performed correctly.

The root cause of the medical event was human error; the licensee wrote the wrong treatment site on the written directive when populating it. The licensee's corrective actions include: (1) the treating interventional radiologist (IR) will specify the intended treatment in writing; (2) the treatment plan review procedure will add a formal review of the written directive by the treating IR physician; and (3) the treatment quality control procedure will include a verbal verification of the treatment site by the treating IR prior to administering the dose.

The licensee performs quality assurance reviews of all its Y-90 administrations at the end of the treatment, which is how this error was identified. Also, a second audit is performed every quarter for all Y-90 administrations. The licensee did not identify any similar cases during these quality assurance reviews.

REPORT DETAILS

1 Program Overview and Inspection History

Henry Ford Hospital (licensee) is authorized to use byproduct material for diagnostic and therapeutic medical procedures under NRC Materials License No. 21-04109-16. Among these procedures are microspheres therapy procedures using Y-90 microspheres, which are performed only at the main hospital at 2799 West Grand Boulevard, in Detroit, Michigan. The purpose of this announced inspection was to review the events surrounding a medical event that occurred during a microspheres procedure on October 3, 2022, and reported to the NRC on October 4, 2022.

2 Radiation Safety Program

2.1 Inspection Scope

The inspector interviewed licensee staff and management personnel concerning the events surrounding a medical event that occurred on October 3, 2022, and reviewed documentation concerning the events leading up to and following the medical event.

2.2 Observations and Findings

On October 3, 2022, the licensee performed a Y-90 TheraSphere treatment to the left liver lobe segment 4 of 22.9 mCi. The procedure did not have any complications, and the required treatment site intended by the Authorized User (AU) was treated. But the written directive for this administration, that was signed and reviewed by the AU, stated treatment site left liver lobe segments 5 and 8. The licensee discovered this error of the treatment site when performing their usual quality assurance procedure after the treatment was done. The licensee notified the NRC Headquarter Operation Center on October 4, 2022, and sent their 15-day report on October 15, 2022. The treatment was reviewed by the AU, Authorized Medical Physicist, and IR physician, and they determined no harm was done to the patient and the intended dose and treatment site were achieved.

One violation was identified as a result of this inspection regarding 10 CFR 35.41 in that the licensee failed to fully implement its procedures for Y-90 microspheres administrations. Specifically, the licensee's procedure for Y-90 microspheres administrations required the licensee to populate the written directive with the proper treatment site. However, the licensee failed to populate the written directive correctly, resulting in a medical event. The licensee implemented corrective actions to prevent a similar violation and medical event.

The root cause of the violation was human error. The licensee utilized a workflow program to document every step of the Y-90 treatment from its beginning with referring the case to the IR, ordering the dose, to completion of the treatment. The error occurred when the licensee was populating the written directive, separate from the workflow program described above, and wrote the wrong treatment site. The licensee failed to correct this error during a "time out" prior to the administration of the Y-90 where they reviewed the dose and administration site with the written directive. However, the treatment went as intended because the licensee relied on the workflow program where all the information was correct.

Corrective actions for this error were implemented by the licensee on November 9, 2022, which included: (1) The treating IR will now specify the intended treatment in writing; (2) the treatment plan review procedure will add a formal review of the written directive by the treating IR physician; and (3) the treatment quality control procedure will include a verbal verification of the treatment site by the treating IR prior to administering the dose.

Since the actual dose was to a different segment than described on the written directive, this constitutes a medical event under Title 10 of *Code of Federal Regulations* (CFR) Section 35.3045(a)(1)(iii)(A) as a dose to the skin or an organ or tissue other than the treatment site that exceeds 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration. Specifically, the written directive specified 23.2 mCi of Y-90 to the left liver lobe segments 5 and 8, but the actual administration was 22.9 mCi of Y-90 to the left liver lobe segment 4. This resulted in no harm to the patient since the intended treatment site of the referring physician was segment 4 all along.

2.3 Conclusions

The inspector identified an apparent violation of 10 CFR 35.41 in that the licensee failed to fully implement its procedures for Y-90 microspheres administrations. Specifically, the licensee's procedure for Y-90 microspheres administrations required the licensee to populate the written directive with the proper treatment site. However, the licensee failed to populate the written directive correctly, resulting in a medical event.

3 Licensee Notifications

3.1 Inspection Scope

The inspector interviewed licensee staff and management personnel concerning the initial notification to the NRC about the medical event and the written report. In addition, the inspector reviewed relevant documentation regarding the event as applicable.

3.2 Observations and Findings

On October 3, 2022, the licensee identified that the administration of the Y-90 microspheres dose might have resulted in a medical event. Licensee staff notified the NRC's Headquarters Operations Center about the potential medical event by telephone on October 4, 2022, meeting the requirement in 10 CFR 35.3045(c) to notify the NRC no later than the next calendar day. Licensee staff followed up during the reactive inspection on October 18, 2022, providing additional details and stating that they had determined that the event did constitute a medical event.

In addition, the referring physician, treating IR physician, AU, and the nuclear medicine physician reviewed the case and indicated that no harm to the patient resulted, because the correct Y-90 TheraSpheres activity was appropriately administered to the correct treatment region. Therefore, this did not require notification of the patient.

On October 15, 2022, the NRC received the licensee's written report. This was within the 15 days required by 10 CFR 35.3045(d) to provide the report to the NRC. The written report contained all required information.

3.3 Conclusions

The inspector identified no violations concerning the licensee's reporting of the medical event to the NRC.

4 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on January 3, 2023. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

#* Alan Jackson, RSO
Keisha McCall PhD, Medical Physicist
Mayur Vaya, Health Physicist
Nicholas Bevins PhD, Medical Physicist

* Attended exit meeting on January 3, 2022.

INSPECTION PROCEDURES USED

IP 87131 – Nuclear Medicine Programs, Written Directive Required