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

February 29, 2024

EN 56619
EN 56666
NMED 230291 (closed)
NMED 230326 (closed)

Alan Jackson, MS, CHP
Radiation Safety Officer
Henry Ford Hospital
2799 West Grand Boulevard
Detroit, MI 48202

SUBJECT: NRC ROUTINE/REACTIVE INSPECTION REPORT
NO. 03002043/2023001(DRSS) AND NOTICE OF VIOLATION – HENRY FORD HOSPITAL

Dear Alan Jackson:

This letter refers to the inspection conducted on July 18 through 20, 2023, and August 22, 2023, at your facilities in Detroit, Dearborn, and West Bloomfield, Michigan, with continued in-office review through February 14, 2024. The purpose of the routine element of this inspection was to review activities performed under your NRC license to ensure that these activities were being performed in accordance with NRC requirements. The purpose of the reactive element of this inspection was to review the circumstances, root and contributing causes, and corrective actions for two medical events that you reported to the NRC on July 12, 2023, and August 8, 2023. The in-office review included an evaluation of your written reports as well as the receipt and review of a report by an expert medical consultant, who performed an independent assessment of the medical event reported on July 12, 2023. The inspector, Ryan Craffey, conducted a final exit meeting by telephone with you on February 21, 2024, to discuss the inspection findings.

The inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations, and with 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 two Severity Level IV violations of NRC requirements occurred.

The violations were 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 first violation, regarding Title 10 of the *Code of Federal Regulations* (10 CFR) 35.610(e) and the failure to ensure that involved staff participate in drills of HDR emergency procedures, is cited in the enclosed Notice of Violation (Notice). The violation is being cited in the enclosed Notice because the inspector identified it during the routine element of the inspection.

The second violation, noted during the reactive element of the inspection, regarding 10 CFR 35.41(a)(2) and the isolated failure to implement written procedures which provided high confidence that intravascular brachytherapy administrations were in accordance with the written directive, is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy. The NRC concluded that the violation met the criteria for an NCV because: (1) you demonstrated initiative in identifying the violation and its root cause; (2) you implemented adequate corrective actions to address the potential for recurrence of a similar violation; (3) the violation is not repetitive because of inadequate corrective action; and (4) was not willful. Therefore, as a credit to your program's performance, no enforcement action will be taken on this matter.

If you contest either of the violations or their significance, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region III; (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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 will be achieved is already adequately addressed on the docket in this letter and its enclosure. 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 above.

In accordance with the NRC's "Agency Rules of Practice and Procedure," in 10 CFR 2.390, a copy of this letter, its enclosures, and your response, if you choose to provide one, 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 or proprietary information so that it can be made publicly available without redaction.

Please feel free to contact Ryan Craffey of my staff if you have any questions regarding this inspection. Ryan can be reached at 630-829-9655 or ryan.craffey@nrc.gov.

Sincerely,

Signed by Edwards, Rhex
on 02/29/24

Rhex A. 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. 03002043/2023001(DRSS)

cc w/encl: Anthony Doemer, Associate RSO
Mayur Vaya, Associate RSO
State of Michigan

Letter to A. Jackson from R. Edwards, dated February 29, 2024.

SUBJECT: NRC ROUTINE/REACTIVE INSPECTION REPORT
NO. 03002043/2023001(DRSS) AND NOTICE OF VIOLATION – HENRY FORD HOSPITAL

DISTRIBUTION w/encl:
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OFFICE	RIII-DRSS		RIII-DRSS					
NAME	RCraffey		REdwards					
DATE	2/29/24		2/29/24					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Henry Ford Hospital
Detroit, MI

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

During an NRC inspection conducted on July 18 through 20, 2023, and August 22, 2023, with continued in-office review through February 14, 2024, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is cited below:

> Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35.610(e) requires that a licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.
>
> Contrary to the above, as of July 18, 2023, Henry Ford Hospital did not ensure that operators, authorized medical physicists, and authorized users participated in drills of the emergency procedures annually. Specifically, the licensee's annual emergency training only required staff to review written emergency procedures.
>
> This is a Severity Level IV violation (Section 6.3).

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 in the subject 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 03002043/2023001(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.

Dated this 29th day of February 2024.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-02043
License No.	21-04109-16
Report No.	03002043/2023001(DRSS)
EN Nos.	56619 and 56666
NMED Nos.	230291 and 230326
Licensee:	Henry Ford Hospital
Facilities:	2799 West Grand Boulevard, Detroit, MI 2800 West Grand Boulevard, Detroit, MI 6777 West Maple Road, West Bloomfield, MI 19401 Hubbard Drive, Dearborn, MI
Inspection Dates:	July 18-20, 2023, and August 22, 2023 In-office review through February 14, 2024
Exit Meeting Date:	February 21, 2024
Inspector:	Ryan Craffey, Senior Health Physicist
Approved By:	Rhex A. Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Security

Enclosure 2

EXECUTIVE SUMMARY

Henry Ford Hospital
NRC Inspection Report 03002043/2023001(DRSS)

This announced inspection included a routine evaluation of activities performed under NRC Materials License No. 21-04109-16, which authorized Henry Ford Hospital to use byproduct material for medical diagnosis, therapy, and clinical research at facilities in Detroit, Dearborn, and West Bloomfield, Michigan, as well as select uses at temporary job sites in NRC jurisdiction.

From the routine element of this inspection, one Severity Level IV violation of Title 10 of the *Code of Federal Regulations* (CFR) 35.610(e) was cited for the failure to ensure that staff involved in high dose rate remote afterloader brachytherapy treatments participated in drills of emergency procedures at least annually.

This inspection also included a reactive element to review the circumstances of two medical events that Henry Ford Hospital reported to the NRC on July 12, 2023, and August 8, 2023, respectively. This review included an assessment of the first medical event by an independent expert medical physics consultant. The consultant concluded that the licensee's response, including an estimate of dose, was reasonable.

From the evaluation of the first medical event, one Severity Level IV violation of 10 CFR 35.41(a)(2) was noted for an isolated and self-identified failure to implement written procedures which provided high confidence that intravascular brachytherapy administrations were in accordance with the written directive. This violation is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy.

No violations were identified from the evaluation of the second medical event, and no harm to the patient was reported or expected from either medical event.

REPORT DETAILS

1 Program Overview and Inspection History

Henry Ford Hospital is authorized by U.S. Nuclear Regulatory Commission (NRC) Broad Scope Materials License No. 21-04109-16 to use byproduct material for medical diagnosis, therapy, and clinical research at facilities in Detroit, Dearborn, and West Bloomfield, Michigan, as well as select uses at temporary job sites in NRC jurisdiction.

At the time of the inspection, the licensee performed diagnostic administrations of radiopharmaceuticals at its main hospital in Detroit (doses were prepared on-site by a nuclear pharmacist using molybdenum-technetium generators), its cancer center across the street (positron emission tomography scans only), and at satellite facilities in West Bloomfield and Dearborn using unit doses from local radiopharmacies. The licensee performed therapeutic administrations of iodine-131 (I-131), radium-223 (Ra-223) Xofigo, and various lutetium-177 (Lu-177) radiopharmaceuticals at the main hospital, including clinical trials, and I-131 only in West Bloomfield. The licensee also performed therapeutic administrations of yttrium-90 (Y-90) microspheres as well as cesium-131 (Cs-131) GammaTile treatment and strontium-90 (Sr-90) intravascular brachytherapy (IVB) treatments at the main hospital, and high dose rate remote afterloading brachytherapy (HDR) treatments at the cancer center. The licensee occasionally used cobalt-57 flood sources at Henry Ford clinics not listed on the license (i.e., temporary job sites) to confirm the presence of lead shielding in the walls of rooms with x-ray units. The licensee disposed of its self-shielded irradiator in June 2023, which it had previously used for research. One authorized user still possessed carbon-14 for research but did not actively use it.

The licensee's Radiation Safety Officer (RSO), based at the main hospital in Detroit, was assisted in their oversight of the radiation protection program by two Associate RSOs, two medical physicists, and an administrative assistant, as well as a Radiation Safety Committee (RSC) which met quarterly to review the status of the program and to evaluate applications for authorized users and uses.

The NRC last performed routine inspections of licensed activities at Henry Ford Hospital on June 11-13, 2018, and May 25-28, 2021. One violation of administrative security requirements was identified in 2018. That violation was closed in 2021 with the completion and confirmation of effective corrective actions. Moreover, the licensee no longer possesses material which would subject it to these requirements. No violations were identified in 2021.

2 Review of Event Number 56619

2.1 Inspection Scope

On July 18-20, 2023, the inspector interviewed involved staff and reviewed procedures, records and equipment related to an IVB treatment reported by the licensee to have met medical event criteria. The inspector continued this review in-office through February 14, 2024, to evaluate the licensee’s written report on the medical event and to request and review a report by an expert medical physics consultant, who performed an independent assessment of the medical event.

2.2 Observations and Findings

A. Sequence of Events and Licensee Response

On the morning of July 11, 2023, the licensee performed an IVB treatment using a Novoste BetaCath device for restenosis at the site of an existing coronary artery stent. Using parameters provided by the referring physician (an interventional cardiologist), a medical physicist prepared a written directive prescribing 23 Gray (Gy) to a 30-mm length of the patient's left circumflex artery at a depth of 2 mm using a 60-mm source train containing Sr-90 (97.8 millicuries at time of manufacture in April 2002, 58.9 millicuries at the time of treatment) for a dwell time of five minutes and 23 seconds at the treatment site. The authorized user (a radiation oncologist) approved the written directive prior to the treatment, and the referring physician began the required catheterization in an interventional cardiology suite to prepare the treatment site for the administration.

On the first attempt at placing a guide catheter, the referring physician realized that the catheter was too short to reach the treatment site and added an extension. The referring physician confirmed via fluoroscopy that the added length was sufficient. The physician noted that the patient's vasculature at the treatment site was unusually tortuous; however, the artery was nevertheless sufficiently open to attempt treatment. The authorized user then fed the delivery catheter with a preloaded Indicator of Source Train (IST; essentially a dummy wire) into the guide catheter and confirmed proper placement of its distal end. The authorized user then removed the IST and connected the BetaCath device to the delivery catheter. The staff performed a time-out to confirm proper equipment setup and treatment parameters; the authorized user then applied hydraulic pressure to push the source train out of the device and into the delivery catheter. The staff heard the distinct click of the source train leaving the device, and after approximately ten seconds (the nominal transit time for the source train to the distal end of the delivery catheter), the authorized user asked the referring physician to confirm that the source train had arrived at the treatment site. The referring physician confirmed, and the timer was started for treatment. After five minutes and 23 seconds, the radiation oncologist applied hydraulic pressure in reverse to return the source train to the device. Several seconds later, the staff heard the distinct click of the source train returning to the device, visually confirmed its return, and performed post-treatment surveys of the device and patient to confirm that the source train had returned to its fully shielded position.

Later that day, the licensee performed a second intravascular brachytherapy treatment using the same BetaCath device on a different patient. Although the same referring physician found the second patient's vasculature to be less tortuous, the same authorized user reported resistance when attempting to deliver the treatment. The authorized user pushed the source train back into its shielded position and tried again. On this second attempt, the referring physician located the source train under fluoroscopy, lodged in the delivery catheter approximately 120 mm short of the intended treatment site. The authorized user again attempted to retract the source; however, this time it would not do so. The referring physician removed the guide catheter from the patient and the authorized user placed the device with delivery catheter still connected into a shielded emergency container for return to and evaluation by the manufacturer.

Later that afternoon, the referring physician voluntarily reviewed fluoroscopy images of both treatments to better understand what might have happened. Upon reviewing

images of the first treatment, the referring physician was unable to locate the source train on any of the saved images. He concluded that he had misinterpreted other markers present to be those of the source train, and that the source train had never arrived at the treatment site. He was unable to determine where the source train had gone for the duration of the treatment, as it could only be confirmed that the source train had left the exit gate of the device and that it had not reached the treatment site.

The referring physician shared these findings with the licensee's radiation safety officer (RSO) and others. The referring physician and authorized user concluded that due to the relatively low, non-ablative and short-range nature of the intended dose, no harm would be expected to the other part of the vasculature presumed to have received the 23-Gy dose, nor any other tissues or organs, which were not expected to have received appreciable dose.

The licensee's medical physics staff later estimated that if the source train had reached the vasculature proximal to the left circumflex artery (the largest-diameter vessel through which the guide and delivery catheter passed), the dose to other tissue could have been as low as 0.46 Gy if the delivery catheter were centered in the vessel. Alternatively, if the guide and delivery catheters had abutted this or another vessel wall, the dose to other tissue could have been as high as 27.83 Gy. The licensee did not determine the relative probability of these possibilities, as no indication of the actual or probable location of the source train during the treatment time was found; however, even the highest postulated dose was still not expected to cause any harm to the patient or their vasculature.

B. Notifications and Reporting

The treatment was performed on July 11, 2023, from 8:46 am to 8:52 am ET. The referring physician discovered the misinterpretation shortly after 4:30 pm ET that day, and promptly notified the patient and the licensee's RSO. The RSO then contacted the NRC's Headquarters Operations Center by telephone at 12:13 pm ET on July 12, 2023, to report the first treatment as a medical event under 10 CFR 35.3045(a)(1)(iii). This notification resulted in Event Number 56619 and was recorded in the Nuclear Materials Events Database under item number 230291.

The licensee submitted its 15-day written report to the NRC on July 26, 2023. The report included the licensee's name, the name of the prescribing physician, a brief description of the event, why the event occurred, the effect, if any on the patient, actions taken to prevent recurrence, and certification that the licensee notified the individual.

The licensee did not consider the attempted second treatment to be a medical event because (1) the treatment was never initiated; and (2) no dose to the skin or an organ or tissue other than the treatment site received a dose exceeding 50 rem for the short time that the source train was present in the delivery catheter.

C. Independent Assessment

Due to the uncertainty surrounding the dose delivered to somewhere other than the treatment site, the NRC contracted the services of an expert medical consultant to perform an independent assessment of the event and its consequences. In a summary of findings dated February 14, 2024, the consultant concluded that the licensee's dose estimate was reasonable, their corrective actions appropriate, and that the dose was insufficient to cause any harm to the patient.

D. Inspector's Assessment

The inspector agreed with the licensee's determination that this treatment met the criteria in 10 CFR 35.3045(a)(1)(iii) to be considered a medical event. The inspector agreed with the licensee's determination of root cause (human error) and contributing factors, which included (1) the quality of the images used to verify correct placement of the catheters and (2) the visual complexity of the images due to the presence of brachytherapy equipment, additional interventional equipment such as the guide tube extension, and pre-existing medical devices.

The inspector reviewed the written directive and other treatment documentation and found that the written directive had been prepared correctly and that the licensee had implemented its procedure for IVB treatments correctly, with one exception – the referring physician incorrectly confirmed that the source train had arrived at the treatment site when asked to do so per procedure. This represented an isolated failure to implement written procedures which provided high confidence that intravascular brachytherapy administrations were in accordance with the written directive, as required by 10 CFR 35.41(a)(2).

This violation would normally be cited as a Severity Level IV in accordance with NRC Enforcement Policy Section 6.3.d.1; however, the NRC concluded that the violation met the criteria in Section 2.3.2 of the Enforcement Policy to be treated as a Non-Cited Violation (NCV) because: (1) the licensee demonstrated initiative in identifying the violation and its root cause (the violation was not self-revealing); (2) the licensee implemented adequate corrective actions (see below) to address the potential for recurrence of a similar violation; (3) the violation was not repetitive because of inadequate corrective action; and (4) was not willful. Therefore, no enforcement action was taken on the matter.

The inspector determined that the root cause of the violation was that of the medical event itself (human error).

As corrective action for both the medical event and the violation, the license revised its IVB treatment policy to require: (1) verbal confirmation from both the attending interventional cardiologist and the radiation oncologist that the source train has reached the intended treatment site; (2) an additional fluoroscopy image acquired using the high-resolution "cine" mode to document that the source train has reached the intended treatment site; and (3) semiannual training for interventional cardiologists, radiation oncologists, and medical physicists involved in IVB treatments on the proper use of IVB devices and applicable regulatory requirements.

2.3 Conclusions

The inspector, informed by an independent expert medical physics consultant, agreed with the licensee's assessment of the medical event. The inspector noted a SLIV violation of 10 CFR 35.41(a)(2) and concluded that it met the criteria to be treated as an NCV.

3 Review of Event Number 56666

3.1 Inspection Scope

On August 22, 2023, the inspector interviewed involved staff and reviewed procedures, records, and equipment related to a microspheres treatment reported by the licensee to have met medical event criteria.

3.2 Observations and Findings

A. Sequence of Events and Licensee Response

On July 31, 2023, a medical physicist prepared a written directive for a Y-90 microspheres treatment for hepatocellular carcinoma. Using parameters developed during a previous mapping study of the patient's hepatic vasculature, the authorized user (a radiation oncologist) prescribed 318.6 Gy to a high perfusion tumoral region within segments 5 and 8 of the right lobe of the patient's liver. The physicist calculated that 26.40 millicuries of Y-90 TheraSpheres would be required to deliver the prescribed dose. The authorized user approved the written directive later that day.

On the morning of August 8, 2023, the licensee performed the intended microspheres treatment. The referring physician, an interventional radiologist, began the required catheterization in an interventional cardiology suite. The licensee's nuclear medicine staff measured the supplied dose at 27.68 mCi and performed pre-treatment surveys of the dose vial using a low-range ion chamber, noting 1.67 milliroentgen per hour (mR/hr) at 30 centimeters. The staff then brought the dose and the administration apparatus into the interventional suite. The referring physician, who was in training at the time to become an authorized user of microspheres, performed the administration under the supervision of an approved authorized user. Both observed as an electronic dosimeter attached to the outside of the delivery apparatus read 2.5 mR/hr prior to delivery and 0.0 mR/hr after delivery. Nuclear medicine staff also performed contact surveys of the apparatus during the treatment with a high-range ion chamber, noting a peak of 25.4 R/hr at the start of delivery, 0.4 R/hr after several intermediate saline flushes, and 0.0 R/hr at the vial after delivery. No issues or abnormalities of any kind were noted during the treatment by any of the staff involved.

The treatment apparatus, dose vial, and other potentially contaminated materials were then packaged into a waste container and returned to the nuclear medicine hot lab. The licensee performed post-treatment surveys of the container with the low-range ion chamber in the same configuration as pre-treatment surveys, noting an average of 0.383 mR/hr at 30 centimeters. Against a decay-corrected pre-treatment reading of 1.64 mR/hr, the post-treatment reading indicated that 23.5% of the supplied dose remained in the container, and that only 78.6% of the prescribed dose had been administered to the patient.

The licensee later performed post-treatment SPECT/CT imaging of the patient and confirmed that the administered dose had gone to the intended treatment site within segments 5 and 8 of the right lobe of the liver. The licensee also performed PET imaging of the waste container and confirmed that over 99% of the residual activity remained in the vial. The licensee reviewed the treatment with involved staff but was unable to find any reason why this amount of residual activity remained in the vial.

The licensee intended to send the waste container (after fully decaying in storage) to the microspheres manufacturer for evaluation of the treatment apparatus.

The referring physician and authorized user were notified of the deviation in administered dose. The referring physician indicated that a therapeutic effect would still be expected from the 250 Gy that had been delivered to the treatment site. The authorized user concurred, citing studies that suggested good treatment response at this dose. The physicians both agreed that no change to the patient's course of treatment would be necessary due to the deviation.

The licensee concluded that no corrective actions were necessary in response to this medical event, as the treatment had been performed in accordance with procedures and all manufacturer's instructions and recommendations.

B. Notifications and Reporting

The treatment was performed on August 8, 2023, at 10:09 am ET. The licensee performed post-treatment surveys of the waste container at 10:32 am. The licensee's RSO was informed shortly thereafter and contacted the NRC's Headquarters Operations Center by telephone at 3:44 pm ET to report the treatment as a medical event under 10 CFR 35.3045(a)(1)(i)(B). This notification resulted in Event Number 56666 and was recorded in the Nuclear Materials Events Database under item number 230326.

The licensee submitted its 15-day written report to the NRC on August 23, 2023. The report included the licensee's name, the name of the prescribing physician, a brief description of the event, why the event occurred, the effect, if any on the patient, actions taken to prevent recurrence, and certification that the licensee notified the individual.

C. NRC Assessment

The inspector agreed with the licensee's determination that this treatment met the criteria in 10 CFR 35.3045(a)(1)(i)(B) to be considered a medical event. The inspector agreed with the licensee that a root cause was not apparent given the information available.

The inspector reviewed the written directive and other treatment documentation and found that the written directive had been prepared correctly and that the licensee had implemented its procedure for TheraSpheres correctly. The inspector agreed that no corrective actions were warranted at this time.

3.3 Conclusions

The NRC agreed with the licensee's assessment of the medical event. The NRC had no other findings from this review.

4 High Dose Rate Remote Afterloading Brachytherapy

4.1 Scope

On July 18, 2023, the inspector visited the cancer center to review the licensee's use and maintenance of a Varian VariSource iX HDR unit. The inspector interviewed

involved staff, evaluated equipment and facilities, and reviewed a selection of treatment and maintenance records.

4.2 Observations and Findings

During a discussion on training for individuals involved in the use of the licensee's HDR unit, the inspector found that staff did not participate in annual drills of HDR emergency procedures, as required by 10 CFR 35.610(e). Rather, the licensee's annual HDR training only required staff to review the written emergency procedures. This was cited as a Severity Level IV violation in accordance with NRC Enforcement Policy Section 6.3.d.3.

The inspector determined that the root cause of the violation was a lack of understanding of regulatory requirements. As corrective action, the licensee completed emergency drill training for all staff currently active in HDR use and confirmed that existing tracking mechanisms and audit activities would be used to ensure that future drills were completed as required.

The inspector also observed the conduct of daily spot checks on the HDR unit, performed independent and confirmatory surveys of the unit and the treatment vault, reviewed documentation of the latest source exchange and full calibration on June 6, 2023, and reviewed written directives, treatment planning and verification documentation, and treatment reports for five cases covering 26 fractions.

4.3 Conclusions

The inspector identified a SLIV violation of 10 CFR 35.610(e).

5 Other Areas Inspected

5.1 Scope

On July 18-20, 2023, the inspector visited the main hospital, cancer center, and satellite facilities in Dearborn and West Bloomfield to observe the conduct of licensed activities, interview involved staff, evaluate equipment and facilities, and review a selection of relevant records.

5.2 Observations and Findings

At the main hospital, the inspector observed the preparation of diagnostic radiopharmaceuticals by the licensee's authorized nuclear pharmacist, including receipt of packages containing licensed material, generator breakthrough testing, dose calibrator checks, and dose quality control activities, as well as the administration of two of the prepared doses. The inspector also observed the preparation and administration of Ra-223 Xofigo and Lu-177 Lutathera therapeutic doses and reviewed the licensee's procedures for the administration of Cs-131 GammaTiles.

At the cancer center, the inspector observed the preparation and administration of F-18 and Cu-64 radiopharmaceuticals, as well as the receipt of packages containing licensed material.

Staff at all locations were knowledgeable of radiation protection principles, wore personnel dosimetry as assigned, and used calibrated and operable radiation detection equipment and effective ALARA measures. The inspector performed independent and

confirmatory surveys at all locations and found no evidence of residual contamination in restricted areas, nor any exposures above regulatory limits to members of the public in unrestricted areas.

The inspector also reviewed a selection of written directives and treatment documentation for therapeutic administrations of radiopharmaceuticals performed at the main hospital and at the satellite facility in West Bloomfield, written directives and treatment documentation for Cs-131 GammaTile therapies, various nuclear medicine records, personnel dosimetry reports, periodic department audits, and radiation safety committee meeting minutes including reviews and approvals of proposed users and uses.

5.3 Conclusions

The inspector had no other findings.

6 Exit Meeting Summary

The inspector presented findings from the routine inspection on July 20, 2023, at the conclusion of the on-site routine inspection. The inspector presented findings from the reactive inspection on February 21, 2024, during a final exit meeting conducted by telephone. The licensee acknowledged the findings presented at both meetings.

LIST OF PERSONNEL CONTACTED

Rich Baginski – Nuclear Medicine Technologist
Mir Basir, DO – Interventional Cardiologist
Warina Branham – Nuclear Medicine Technologist
Ishani Dalal, MD – Senior Staff Radiologist
Anthony Doemer, MS – Director of Clinical Physics, Associate RSO
Mohamed Elshaikh, MD – Radiation Oncologist
Stephen Gardner, MS – Senior Associate Physicist
Jessie Huang-Vredevoogd, PhD – Medical Physicist
Alan Jackson, MS, CHP – Radiation Safety Officer
Frank Lico – Nuclear Medicine Technologist
Keisha McCall, PhD – Medical Physicist
David McVinnie, MD – Interventional Radiologist
Jeanne Moceri-Mitchell – Nuclear Medicine Technologist
Mayur Vaya – Medical Physics Assistant, Associate RSO
Gordon Wong – Nuclear Pharmacist
Tara Stewart – Nuclear Medicine Technologist
Thaddeus Fitzpatrick – Nuclear Medicine Technologist

Attended exit meeting on February 21, 2024

INSPECTION PROCEDURES USED

87103: Inspection of Nuclear Material Licensees Involved in an Incident or Bankruptcy Filing
87130: Nuclear Medicine Programs
87132: Brachytherapy Programs