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

November 6, 2023

Brian Hicks
Director of Radiology
Elkhart General Hospital
600 East Blvd.
Elkhart, IN 46515

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03017305/2023001(DRSS) AND NOTICE OF VIOLATION – ELKHART GENERAL HOSPITAL

Dear Brian Hicks:

This letter refers to the inspection conducted on August 22, 2023, at your Elkhart, Indiana, facility with continued in-office review through October 24, 2023. The purpose of the 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 in-office review was to evaluate information not available at the time of the on-site inspection. This letter presents the results of the inspection. Elizabeth Tindle-Engelmann of my staff conducted a virtual exit meeting with your staff on October 24, 2023, to discuss the inspection findings.

This 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 violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violations are being cited in the enclosed Notice because the inspector identified them.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with the NRC's "Agency Rules of Practice and Procedure" 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 Elizabeth Tindle-Engelmann of my staff if you have any questions regarding this inspection. Elizabeth can be reached at 630-829-9681 or Elizabeth.Tindle-Engelmann@nrc.gov.

Sincerely,

Signed by Edwards,
Rhex on 11/06/23

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

Docket No. 030-17305
License No. 13-18879-01

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03017305/2023001(DRSS)

cc w/encl: Daniel J. Archambeault, RSO
Tyler First, Manager of Imaging Services
Sharon Updike, Consultant
State of Indiana

Letter to B. Hicks from R. Edwards, dated November 6, 2023.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03017305/2023001(DRSS) AND NOTICE OF VIOLATION – ELKHART GENERAL HOSPITAL

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ADAMS Accession Number: ML23306A259

OFFICE	RIII-DRSS		RIII-DRSS					
NAME	ETindle-Engelmann		REdwards					
DATE	11/6/23		11/6/23					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Elkhart General Hospital
Elkhart, IN

License No. 13-18879-01
Docket No. 030-17305

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on August 22, 2023, with continued in-office review through October 24, 2023, two 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) 20.1502(a)(1) requires, in part, that each licensee monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

   Title 10 CFR 20.1201(a)(2)(ii) states, in part, the annual limits to the skin of the whole body, and to the skin of the extremities is a shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

   Contrary to the above, for periods between August 2, 2021, and August 22, 2023, the licensee failed to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and did not require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a). Specifically, one authorized user of yttrium-90, whose occupational exposure to licensed and unlicensed sources of radiation was likely to exceed 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii), often failed to wear their supplied extremity dosimeter, thereby preventing the licensee from monitoring their occupational shallow-dose equivalent exposure to the skin of the whole body or the skin of the extremity.

   This is a Severity Level IV violation (Enforcement Policy Section 6.7).

B. 10 CFR 19.12(a)(3) requires, in part, that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material.

   Contrary to the above, as of August 22, 2023, the licensee failed to instruct all individuals, who in the course of employment were likely to receive in a year an occupational dose in excess of 100 mrem, in the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material. Specifically, the licensee failed to provide instruction to one individual, who in the course of employment as an interventional radiologist yttrium-90 authorized user was likely to receive in a year an occupational dose in excess of 100 millirem, on the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and radioactive material.

   This is a Severity Level IV violation (Enforcement Policy Section 6.3).

Pursuant to the provisions of 10 CFR 2.201, Elkhart General Hospital is hereby required to submit a written statement or explanation 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 of Violation (Notice). Additionally, please provide an electronic copy of your response via email to Elizabeth Tindle-Engelmann at Elizabeth.tindle-engelmann@nrc.gov. This reply should be clearly marked as a "Reply to a Notice of Violation, IR 03017305/2023001(DRSS)" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 6th day of November 2023.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-17305
License No.	13-18879-01
Report No.	03017305/2023001(DRSS)
Licensee:	Elkhart General Hospital
Facility:	600 East Blvd. Elkhart, IN 46515
Inspection Dates:	Onsite August 22, 2023; in-office review through October 24, 2023.
Exit Meeting Date:	October 24, 2023
Inspector:	Elizabeth Tindle-Engelmann, Health Physicist
Approved By:	Rhex Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Security

EXECUTIVE SUMMARY

Elkhart General Hospital
NRC Inspection Report 03017305/2023001(DRSS)

This was a routine inspection of licensed activities involving the medical use of byproduct material. Elkhart General Hospital was a medical facility located in Elkhart, Indiana. The U.S. Nuclear Regulatory Commission (NRC) License No. 13-18879-01 authorized Elkhart General Hospital to possess and use byproduct material for various medical uses including diagnostic and therapeutic radiopharmaceuticals and the medical use of yttrium-90 (Y-90) microspheres as permitted by Title 10 of the Code of Federal Regulations (10 CFR) Part 35.1000.

On August 22, 2023, the inspector identified two violations. The violations concerned the licensee's failure to: (1) monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee since they did not require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii); and (2) provide instruction to one individual, who in the course of employment as an interventional radiologist yttrium-90 authorized user, was likely to receive in a year an occupational dose in excess of 100 millirem.

REPORT DETAILS

1 Program Overview and Inspection History

The inspector reviewed the license application and supporting documents. Additional information was gathered through direct observation of licensed activities, interviews with the licensee's staff, a review of selected records, and a tour of the facility.

1.2 Observations and Findings

Elkhart General Hospital was authorized under NRC Materials License No. 13-18879-01 to possess and use byproduct material for various medical uses including diagnostic and therapeutic radiopharmaceuticals as permitted by 10 CFR 35.100 – 300 and the medical use of Y-90 microspheres as permitted by 10 CFR Part 35.1000. The licensee was a medical facility in Elkhart, Indiana. They had one hospital and one outpatient clinic. The licensee had 28 authorized users (AUs) on their license. The licensee's Radiation Safety Officer (RSO) was onsite as needed. The licensee utilized a consultant to perform program reviews, equipment calibrations, and additional oversight of the radiation protection program. The licensee had one nuclear medicine department and was in the process of building a PET department. The licensee's staff administered approximately 10 SPECT doses per day. Unit doses of primarily technetium-99m were obtained from a licensed radiopharmacy. Other radionuclides such as indium-111, iodine-123, and iodine-131 were obtained from a licensed radiopharmacy on an as needed basis. The licensee administered approximately one Y-90 dose per month and approximately one other therapeutic dosage of byproduct material per month.

The last routine inspection of the license was in August of 2021, and two violations were identified. NRC Inspection Report 03017305/2021001(DNMS) cited two violations concerning the licensee's failure to: (1) perform a prospective evaluation demonstrating that two unmonitored individuals were not likely to receive in excess of 10% of the allowable limits for the extremities in 10 CFR Part 20 or provide dosimetry, as required by License Condition 13; and (2) provide instruction to two interventional radiologists who were likely to receive in a year, an occupational dose in excess of 100 millirem, as required by 10 CFR 19.12(a)(3). The previous routine inspection was conducted in October of 2018, and no violations were identified.

2 Radiation Safety Program

2.1 Inspection Scope

On August 22, 2023, the inspector visited Elkhart General Hospital's facility to review the implementation of the licensee's radiation safety program. The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with NRC rules, NRC regulations, and the conditions of the license. The inspector toured the main hospital, observed licensed activities, conducted interviews, and reviewed selected records.

2.2 Observations and Findings

The inspector only toured the main hospital since the outpatient clinic was not performing any licensed activities on the day of the inspection. The inspector observed the following tasks: ambient radiation level surveys and package return procedures. The

licensee demonstrated the following tasks: decay in storage procedures, dose preparation and administration, package receipt procedures, and spill response. The inspector reviewed a sample of records including the following items: area surveys, dose calibrator calibrations, dosimetry, package receipts, package returns, program reviews, radiation safety committee meeting minutes, sealed source leak tests and inventories, select policies and procedures, spill reports, training, and written directives.

Based on the inspection, two violations of NRC requirements were identified and one previous violation was closed.

Violation of 10 CFR 20.1502(a)(1)

NRC Inspection Report 03017305/2021001(DNMS) identified a violation concerning the licensee's failure to perform a prospective evaluation demonstrating that two unmonitored individuals were not likely to receive in excess of 10% of the allowable limits for the extremities in 10 CFR Part 20 or provide dosimetry, as required by License Condition 13 of NRC License No. 13-18879-01, Amendment 65. As a corrective action, the licensee conducted a retrospective evaluation of the extremity exposures for two interventional radiologists Y-90 AUs and determined they were likely to exceed 10% of the allowable extremity dose. Based on this finding, the licensee provided extremity monitoring to interventional radiologists who use yttrium-90. The inspector determined that these corrective actions were complete which closed the violation of Condition 13 of NRC License No. 13-18879-01, Amendment 65 that was issued in 2021. While the licensee had made an evaluation and issued extremity dosimetry, the inspector identified one violation related to the use of extremity dosimetry.

During review of the dosimetry records and Y-90 written directives, the inspector observed that the licensee had one active Y-90 AU and that this individual infrequently wore extremity monitors. However, they received occupational dose while working with unlicensed sources of radiation, such as fluoroscopy machines, on a regular basis and sources of licensed radiation, such as Y-90, on a monthly basis. Specifically, the inspector observed that one AUs of Y-90 whose occupational exposure to licensed and unlicensed sources of radiation was likely to exceed 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii) often failed to wear their supplied extremity dosimeter. The individual's failure to wear the monitoring devices prevented the licensee from monitoring their occupational shallow-dose equivalent exposure to the skin of any extremity. This is a violation of 10 CFR 20.1502(a)(1) which requires, in part, that each licensee monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii).

Violation of 10 CFR 19.12(a)(3)

NRC Inspection Report 03017305/2021001(DNMS) identified a violation concerning the licensee's failure to provide instruction to individuals who were likely to receive in a year an occupational dose in excess of 100 millirem. The licensee's corrective actions included: (1) developing an annual training program for interventional radiologists on the radiation safety program and proper use of dosimetry; and (2) providing instruction to interventional radiologists. The inspector reviewed the training and determined that the licensee completed the corrective actions after the last inspection in 2021. However, when a new Y-90 AU interventional radiologist began working at the facility the licensee did not require that the individual receive the training which resulted in the previously

described violation of 10 CFR 20.1502(a)(1). The licensee's failure to provide instruction to individuals who in the course of employment were likely to receive in a year an occupational dose in excess of 100 millirem, on the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and radioactive material is a violation of 10 CFR 19.12(a)(3). The licensee received a similar violation for this requirement in NRC Inspection Report 03017305/2021001(DNMS).

2.3 Conclusions

Two violations were identified regarding the licensee's failure to: (1) monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee since they did not require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii); and (2) provide instruction to one individual, who in the course of employment as an interventional radiologist Y-90 AU, was likely to receive in a year an occupational dose in excess of 100 millirem. The inspector closed one violation from NRC Inspection Report 03017305/2021001(DNMS).

3 Independent Radiation Measurements

Independent radiation surveys were conducted at the inspected facility. The survey results were consistent with the licensee's postings, the licensee's survey results, and applicable regulatory limits.

Instrumentation:	Model: RadEye G
	Serial Number: 30653
	Calibration Expiration: May 9, 2024

4 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on August 22, 2023. Upon completion of in-office review, a virtual exit meeting was held on October 24, 2023, with the licensee. 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

Brian Hicks, Director of Radiology
\# Tyler First, Manager of Imaging Services
\# Daniel Archambeault, RSO
\# Sharon Updike, Consultant

\# Attended exit meeting on October 24, 2023.

LIST OF ACRONYMS AND ABBREVIATIONS USED

AU	authorized user
NRC	Nuclear Regulatory Commission
RSO	Radiation Safety Officer
Y-90	yttrium-90
10 CFR	Title 10 of the *Code of Federal Regulations*

INSPECTION PROCEDURES USED

IP 87130 – Nuclear Medicine Programs
IP 87132 – Brachytherapy Programs