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

December 8, 2021

Mr. Brian Hicks
Director, Imaging Services
Elkhart General Hospital
600 East Blvd.
Elkhart, IN 46515

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-17305/2021001(DNMS) AND NOTICE OF VIOLATION – ELKHART GENERAL HOSPITAL

Dear Mr. Hicks:

On June 22, 2021, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Elkhart, Indiana hospital. This inspection included continued in-office review through November 12, 2021. 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 information related to your radiation safety program that was unavailable at the time of the on-site inspection. Ms. Deborah A. Piskura of my staff conducted a final exit meeting by telephone with you on November 12, 2021, to discuss the inspection findings.

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 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 involved the failures 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 violations were identified by the inspector and are being cited in the enclosed Notice of Violation (Enclosure 1).

The NRC requested your staff to perform a retrospective evaluation of the radiation extremity dose received by two interventional radiology physicians from 2018 to year-to-date 2021 who were authorized users of yttrium-90. Based on the results of your dose reconstruction, no individual exceeded an annual extremity exposure greater than ten percent of the NRC's limits. The root cause of the failure to perform an evaluation that demonstrated individuals were not likely to receive an extremity dose in excess of 10% of the limits was an inappropriate reliance

on information in journal articles and package inserts, instead of the use of readily obtainable dose-rate and time and motion information from actual treatments performed by the radiologists and on exposures to the radiologists from other radiation sources. The root cause of the violation involving the failure to provide annual training to the interventional radiologists was attributed to a misunderstanding of the regulatory requirements which were applicable to physicians and the failure to recognize that the training of physicians as part of medical school and clinicals did not include NRC training in the regulatory requirements.

Your corrective actions to restore compliance and to prevent recurrence included: (1) conducting a retrospective evaluation of the extremity exposures for your two interventional radiologists authorized to use yttrium-90; (2) providing extremity monitoring to your interventional radiologists who use yttrium-90; (3) developing an annual training program for interventional radiologists on your radiation safety program and proper use of dosimetry; and (4) providing instruction to your interventional radiologists on October 4, 2021.

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 will be achieved is already adequately addressed on the docket in this letter and the enclosed 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 10 CFR 2.390 of the NRC's "Rules of Practice," 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.

Please feel free to contact Ms. Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

Michael A. Kunowski Signed by Kunowski, Michael on 12/08/21

Michael A. Kunowski, Chief
Materials Inspection Branch

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

Enclosures:
1. Notice of Violation
2. Inspection Report 030-17305/2021001(DNMS)

cc w/encl: Mr. Daniel Archambeault, Radiation Safety Officer
State of Indiana

Letter to Brian Hicks from Michael Kunowski dated, December 8, 2021.

SUBJECT: NRC INSPECTION REPORT NO. 030-17305/2021001(DNMS) AND NOTICE OF VIOLATION – ELKHART GENERAL HOSPITAL

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OFFICE	RIII-DNMS		RIII-DNMS						
NAME	DPiskura:brt:gp		MKunowski						
DATE	12/1/2021		12/8/21						

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 June 22, 2021, with continued in-office review through November 12, 2021, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Condition 13 of NRC License No. 13-18879-01, Amendment 65, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the listed documents, including the licensee's application dated February 23, 2011.

Subitem "Occupational Dose" of Item 10, "Radiation Protection Program," of application dated February 23, 2011, states, in part, "either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess 10 percent of 10 CFR Part 20, or we will provide dosimetry that meets the requirements listed under Criteria in NUREG-1556, Vol. 9, Revision 2, Consolidated Guidance About Materials Licensees: Program Specific Guidance About Medical Licensees."

Contrary to the above, as of October 14, 2021, the licensee failed to perform a prospective evaluation demonstrating that unmonitored individuals were not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20, or to provide dosimetry to these individuals. Specifically, an evaluation was not performed to demonstrate that two interventional radiologists would likely not receive an extremity dose in excess of 10 percent of the dose limit in 10 CFR Part 20 nor were extremity dosimeters provided to them.

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

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 October 3, 2021, the licensee failed to provide instruction to two individuals, who in the course of employment as interventional radiologists 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/or radioactive material.

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

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 this letter. 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 030-17305/2021001(DNMS)" 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 8 day of December 2021.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-17305
License No.	13-18879-01
Report No.	030-17305/2021001(DNMS)
Licensee:	Elkhart General Hospital
Address:	P.O. Box 1329 Elkhart, IN 46515
Location Inspected:	Main Hospital 600 East Boulevard Elkhart, Indiana
Inspection Date:	June 22, 2021
Exit Meeting Date:	November 12, 2021
Inspector:	Deborah A. Piskura, Senior Health Physicist
Approved By:	Michael A. Kunowski, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Elkhart General Hospital
NRC Inspection Report 030-17305/2021001(DNMS)

This was a routine inspection conducted on June 22, 2021, to review the licensed activities at Elkhart General Hospital, Elkhart, Indiana. The purpose of the inspection was to evaluate the licensee's performance and compliance with NRC regulations and license conditions. The inspector reviewed several program areas including security, radiation protection, personnel monitoring, posting, labeling, and training. The inspection included in-office review through November 12, 2021, of the licensee's dose reconstruction data spanning several years for two interventional radiologists.

At the NRC's request, the licensee reassessed the reported radiation dose and performed a retrospective evaluation of the radiation dose to the extremities received by two interventional radiologists who were authorized users of yttrium-90. The licensee's evaluation addressed the radiation dose received by them from 2018 to year-to-date 2021. The licensee's evaluation concluded that no individual likely exceeded, in one year, a radiation dose in excess 10 percent of 10 CFR Part 20 limits for the extremities.

Two violations of NRC requirements were identified during this inspection. The violations involved the licensee's failures to: (1) conduct a prospective evaluation demonstrating that two unmonitored interventional radiologists using yttrium-90 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 individuals 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).

Following the onsite inspection, the licensee implemented several corrective actions to address the violations, which included revising licensee policies, providing extremity monitoring to interventional radiologists who use yttrium-90, and providing individuals who were likely to receive in one year, an occupational dose in excess of 100 millirem, instruction regarding the licensee's policies regarding the use of personnel monitoring devices.

REPORT DETAILS

1 Program Overview and Inspection History

Elkhart General Hospital is authorized under NRC Materials License No. 13-18879-01 for materials permitted in Title 10 of the Code of Federal Regulations (CFR) Sections 35.100, 35.200, 35.300, and 35.1000 limited to yittrium-90 microspheres. The hospital retained a consultant medical physicist from a sister hospital within the healthcare system who served as the radiation safety officer. The licensee's nuclear medicine department was staffed with four technologists who performed approximately 200 diagnostic nuclear medicine procedures monthly. The licensee performed a full spectrum of studies and received unit doses of technetium-99m from a licensed radiopharmacy. The hospital administered numerous iodine-131 dosages (capsules only) for whole body follow-up studies, hyperthyroid, and thyroid cancer treatments; all patients were released in accordance with the criteria specified in 10 CFR 35.75. The department also administered 3-5 yittrium-90 microspheres (SIR-Spheres) treatments annually. No alpha or beta-emitting radiopharmaceutical therapies were administered at the time of this inspection.

The last routine inspections were conducted on August 30, 2018, and September 20, 2016; no violations of NRC requirements were identified during these inspections.

2 Management Oversight and the Radiation Safety Committee

2.1 Inspection Scope

The inspector reviewed the licensee’s management of the radiation safety program and the radiation protection program reviews. The inspector interviewed selected licensee staff, the consultant physicist, and the radiation safety officer. The inspector also reviewed selected audit reports for 2018 to year-to-date 2021.

2.2 Observations and Findings

The hospital established a radiation safety committee, which met quarterly to review and approve authorized physician users. The meeting minutes indicated the committee member attendance and the topics.

The licensee retained the services of a consultant who audited the radiation safety program on a quarterly basis; the last audit was conducted on May 18 and 20, 2021, with no findings. The consultant presented her audit findings during the radiation safety committee meetings. The radiation safety officer reviewed and signed the consultant’s audit reports.

2.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector identified no violations of NRC requirements.

3 Personnel Monitoring Program for Interventional Radiologists

3.1 Inspection Scope

This inspection included a review of the licensee's dosimetry program with focus on the interventional radiologists. The inspector reviewed records, procedures, and documents maintained by the licensee, observed licensed activities, and interviewed selected licensee personnel. The inspector reviewed information provided by the licensee following the onsite inspection.

3.2 Observations and Findings

Dosimetry is required for individuals likely to receive in one year from sources external to the body a dose in excess of 10% of the applicable regulatory limits in 10 CFR 20. 1201. In order to demonstrate that dosimetry is not required, a licensee must perform a prospective evaluation to demonstrate that its workers are not likely to exceed 10% of the applicable annual limits before allowing workers to perform their tasks with licensed materials. A licensee needs to evaluate the doses which its workers might receive to assess whether dosimetry is required.

The inspector identified that the licensee did not perform a prospective evaluation or provide extremity monitoring to two authorized users who worked as interventional radiologists. These interventional radiologists worked with yttrium-90 microspheres (licensed activities) and x-ray or fluoroscopy procedures (non-licensed activities) at the licensee's main hospital.

At the conclusion of the onsite inspection, the inspector requested the licensee to conduct a dose assessment for these interventional radiologists. The licensee provided its evaluation to the NRC in its non-public letter dated October 15, 2021.

In order to assess the radiation dose to the extremities for the two IR physicians, the licensee gathered readily retrievable information on the number of yttrium-90 procedures administered for the years 2018 to date. The licensee conducted interviews with the IR physicians to gather information regarding the standard setup for its yttrium-90 procedures. The licensee used exposure rate data from the package inserts to estimate the finger exposure at the point of injection. The licensee included the dose contribution from fluoroscopy during the catheter positioning, the preparation of the Administration Set, the infusion of the microspheres into the patient and the withdrawal of the catheter. A summary of the licensee's radiation dose evaluation is provided in table below. The licensee's evaluation concluded that there were no extremity exposures in excess of 10 percent of NRC's regulatory limit of 50 rem total shallow dose equivalent for any IR physician during the evaluation period. However, in September 2021, the licensee elected to provide extremity monitoring to its interventional radiologists who were authorized users of yttrium-90.

Licensee's extremity dose estimates in millirem

	2018	2019	2020	YTD 2021
IR 1	170	0	165	0
IR 2	0	0	17	0

The inspector evaluated the licensee's radiation dose estimates and determined that the licensee's approach and assumptions were sound and comprehensive. The inspector found that the licensee's methodology would not be expected to underestimate the extremity dose and resulted in conservative but reasonable radiation dose estimates for the two IR physicians.

Condition 13 of NRC License No. 13-18879-01, amendment 65, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the listed documents, including the licensee's application dated February 23, 2011.

Item 10, "Radiation Protection Program-Occupational Dose," of Application dated February 23, 2011, states, in part, "either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess 10 percent of 10 CFR Part 20, or we will provide dosimetry that meets the requirements listed under Criteria in NUREG-1556, Vol. 9, Revision 2, Consolidated Guidance About Materials Licensees: Program Specific Guidance About Medical Licensees."

The licensee's failure to perform a prospective evaluation demonstrating that two interventional radiologists who were unmonitored for extremity exposure from yttrium-90 were not likely to receive, in one year, a radiation dose to the extremities, in excess of ten percent of the allowable limits in 10 CFR Part 20 or provide extremity dosimetry to these two interventional radiologists is a violation of License Condition 13.

The root cause of the failure to perform an evaluation that demonstrated individuals were not likely to receive an extremity dose in excess of 10% of the limits was an inappropriate reliance on information in journal articles and package inserts, instead of the use of readily obtainable dose-rate and time and motion information from actual treatments performed by the radiologists and on exposures to the radiologists from other radiation sources.

The inspector determined that the licensee provided annual training on the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material to its personnel who in the course of their employment who were likely to receive, in a year, an occupational dose in excess of 100 millirem. These groups included the nuclear medicine department. However, the licensee did not provide annual training to its interventional radiology physicians who in the course of their employment also were likely to receive in a year, an occupational dose in excess of 100 millirem. The licensee assumed that interventional radiologists were not required to receive annual training because during the course of their education in medical school and follow-up clinical programs, these physicians would have received instruction in the NRC's regulations and radiation safety training specific to yttrium-90.

Title 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.

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/or radioactive material is a violation of 10 CFR 19.12(a)(3).

The licensee implemented several actions to restore compliance including: (1) conducting a retrospective evaluation of the extremity exposures for the two interventional radiologists authorized to use yttrium-90; (2) providing extremity monitoring to interventional radiologists who use yttrium-90; (3) developing an annual training program for interventional radiologists on the licensee's radiation safety program and the use of extremity dosimetry; and (4) providing instruction to the interventional radiologists on October 4, 2021.

3.3 Conclusions

The inspector identified two violations involving the licensee's failures 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 licensee implemented corrective actions for these violations.

4 Other Areas Inspected

4.1 Inspection Scope

The inspector observed licensed activities, interviewed licensee personnel, and reviewed selected records concerning use and security of licensed materials, and other aspects of the radiation safety program. The inspector observed use of byproduct material, including the administration of several dosages for various nuclear medicine studies. The inspector performed confirmatory surveys in areas of radioactive materials use and in public areas.

4.2 Observations and Findings

The inspector observed that the licensee personnel maintained constant surveillance of its licensed material. In addition, the nuclear medicine hot lab remained secured. The inspector determined that the consultant provided annual training to all staff working with or in the vicinity of licensed material. Through interviews, the inspector determined that the licensee staff understood security requirements for licensed material.

The inspector reviewed written directives for several iodine-131 and yttrium-90 patient treatments. The licensee documented the written directive, the verification of the patient identity, and dosage verification. No medical events were identified.

The inspector examined the sealed sources in the licensee's possession. Each source container was noted to bear a clearly visible label identifying the radionuclides and source activities. The licensee's consultant performed inventories and leak tests of the sealed sources and documented the results in his reports.

The licensee posted caution signs, NRC-3 forms, and license documents in accordance with 10 CFR Parts 19 and 20. The hot lab was also posted with emergency/decontamination procedures and an approved dosage chart. During facility tours the inspector noted no evidence of eating, drinking, smoking, or cosmetic application in restricted areas.

The licensee monitored radiation exposure to nuclear medicine technologists using whole body and extremity personnel dosimeters provided by an accredited laboratory. The dosimeters were exchanged on a monthly basis. All technologists were advised of their exposure data at least annually. The inspector reviewed a sampling of dosimetry reports and determined that all monitoring results were below Part 20 occupational exposure limits.

The licensee possessed several calibrated survey instruments used by the nuclear medicine staff. Confirmatory surveys indicated radiation levels consistent with licensee survey records and postings.

4.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector determined that no violations of NRC requirements were identified.

5 Exit Meeting Summary

The NRC inspector presented the preliminary inspection findings following the onsite inspection on June 22, 2021. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented. The final exit meeting was subsequently conducted via telephone on November 12, 2021, which included a discussion of the violations and the licensee's actions taken to restore compliance.

LIST OF PERSONNEL CONTACTED

Eric Amrein, CNMT
#*Daniel Archambeault, M.S., Radiation Safety Officer
Tyler First, CNMT
#*Brian Hicks, Director, Imaging Services
Bobby Lentsch, CNMT
*Phil S. Morris, Manager, Imaging Services
Greenlee Robinson, CNMT
*Sharon Updike, MHP, DABR, Consultant Physicist, Medical Physics Consultants

#Attended the on-site exit meeting on June 22, 2021
*Participated in the November 12, 2021, final exit teleconference

INSPECTION PROCEDURES USED

IP 87130, Nuclear Medicine Programs, Written Directive Not Required
IP 87131, Nuclear Medicine Programs, Written Directive Required
IP 87132, Brachytherapy Programs