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

November 19, 2021

Mr. Chris Karam
President
Saint Joseph Regional Medical Center
5215 Holy Cross Pkwy.
Mishawaka, IN 46545

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-13685/2021001(DNMS) AND NOTICE OF VIOLATION – SAINT JOSEPH REGIONAL MEDICAL CENTER

Dear Mr. Karam:

On June 23, 2021, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Mishawaka, Indiana hospital. This inspection included continued in-office review through October 28, 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 your consultant and Ms. Sharon Updike and Mr. David Hofstra of your staff on October 28, 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 three 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 three 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 three interventional radiology physicians during the calendar years 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 a 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 training in the NRC regulatory requirements.

Your corrective actions to restore compliance and to prevent recurrence included: (1) conducting a retrospective evaluation of the extremity exposures for your three 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 the proper use of dosimetry; and (4) providing instruction to your interventional radiologists on September 29 and October 27, 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 enclosure, 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 11/19/21

Michael A. Kunowski, Chief
Materials Inspection Branch

Docket No. 030-13685
License No. 13-02650-02

Enclosures:
1. Notice of Violation
2. Inspection Report No. 030-13685/2021001(DNMS)

cc w/encl: State of Indiana

Letter to Chris Karam from Michael Kunowski dated, November 19, 2021.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-13685/2021001(DNMS) AND NOTICE OF VIOLATION– SAINT JOSEPH REGIONAL MEDICAL CENTER

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| OFFICE | RIII-DNMS | | RIII-DNMS | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| NAME | DPiskura:brt | | MKunowski | | | | | | |
| DATE | 11/16/2021 | | 11/19/21 | | | | | | |

**OFFICIAL RECORD COPY**

# NOTICE OF VIOLATION

Saint Joseph Regional Medical Center
Mishawaka, IN

License No. 13-02650-02
Docket No. 030-13685

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on June 23, 2021, with continued in-office review through October 28, 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. 13-02650-02 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 letters dated April 10, 2014.

Item 10, "Radiation Protection Program-Occupational Dose," of letter dated April 10, 2014, 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 of 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 June 23, 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 three 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 June 23, 2021, the licensee failed to provide instruction to three individuals who 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 violation 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 030-13685/2021001(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 19 day of November 2021.

**U.S. Nuclear Regulatory Commission**
**Region III**

| | |
|---|---|
| Docket No. | 030-13685 |
| License No. | 13-02650-02 |
| Report No. | 030-13685/2021001(DNMS) |
| Licensee: | Saint Joseph Regional Medical Center |
| Address: | 5215 Holy Cross Pkwy.<br>Mishawaka, Indiana |
| Locations Inspected: | Main Hospital<br>5215 Holy Cross Pkwy.<br>Mishawaka, Indiana<br><br>611 E. Douglas Rd.<br>Mishawaka, Indiana<br><br>53940 Carmichael Dr.<br>South Bend, Indiana |
| Inspection Date: | June 23, 2021 |
| Exit Meeting Date: | October 28, 2021 |
| Inspector: | Deborah A. Piskura, Senior Health Physicist |
| Approved By: | Michael A. Kunowski, Chief<br>Materials Inspection Branch<br>Division of Nuclear Materials Safety |

Enclosure 2

## EXECUTIVE SUMMARY

### Saint Joseph Regional Medical Center
### NRC Inspection Report 030-13685/2021001(DNMS)

This was a routine inspection conducted on June 23, 2021, to review the licensed activities at Saint Joseph Regional Medical Center, Mishawaka, 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, training, posting, and labeling. The inspection included in-office review through October 28, 2021, of the licensee's dose reconstruction data spanning several years for two interventional radiologists.

At the NRC's request, the licensee performed a retrospective evaluation of the radiation dose to the extremities received by three interventional radiologists who were authorized users of yttrium-90. The evaluation addressed the radiation dose received by the radiologists from 2018 to year-to date 2021 and 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) perform a prospective evaluation demonstrating that three unmonitored individuals were not likely to receive in excess of 10% of the allowable limit 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

Saint Joseph Regional Medical Center (licensee) is authorized under NRC Materials License No. 13-02650-02 for materials in Title 10 of the Code of Federal Regulations (CFR) Sections 35.100, 35.200, 35.300, 35.400, and 35.1000 limited to yittrium-90 (Y-90) microspheres. The licensee was authorized to conduct licensed activities at 5 locations of use in northern Indiana. The licensee's nuclear medicine department at the main hospital was staffed with three technologists who performed approximately 250 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 5 to 10 Y-90 microspheres (TheraSpheres and SIR-Spheres) treatments annually. No alpha or beta-emitting radiopharmaceutical therapies were administered at the time of this inspection.

During the last routine inspection conducted on August 28-29, 2018, one non-cited violation was identified involving the licensee's failure to perform area surveys in accordance with the licensee's procedures referenced in License Condition 13.A. The previous routine inspection was conducted on September 22, 2016; no violations of NRC requirements were identified during this inspection.

### 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 the 2019 to the year-to-date 2021 period.

#### 2.2 Observations and Findings

The hospital established a radiation safety committee, which met quarterly to review the radiation safety program, personnel exposure histories and trends, and the ALARA program. The meeting minutes indicated the committee member attendance and the topics.

The licensee retained the services of a consultant who served as the radiation safety officer and 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.

#### 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 (IRs). 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 licensee had earlier concluded that dosimetry was not needed for IRs using Y-90 but the inspector noted that this undocumented conclusion was based on information in technical journal articles and package inserts rather than on readily obtainable dose-rate and time and motion information from actual treatments performed by the IRs and on exposures to the IRs from other (non-NRC licensed) radiation sources. These IRs not only worked with Y-90 microspheres (NRC-licensed) but also conducted x-ray or fluoroscopy procedures (non-NRC licensed) 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 IRs. The licensee provided its initial radiation dose evaluation to the NRC in its letter dated August 31, 2021, received on September 14, 2021.

In order to make radiation dose assessment to the extremities for the three radiologists, the licensee gathered readily retrievable information on the number of Y-90 procedures administered for the years 2018 to date. The licensee conducted interviews with the radiologists to gather information regarding the standard setup for its Y-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 Y-90 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 of the three radiologists during the evaluation period. However, in June 2021, the licensee elected to provide extremity monitoring to its interventional radiologists who were authorized users of Y-90.

**Licensee's extremity dose estimates in millirem**

| | 2018 | 2019 | 2020 | YTD 2021 |
|---|---|---|---|---|
| IR 1 | 563 | 6.1 | 0 | 287 |
| IR 2 | 141 | 389 | 106 | 144 |
| IR 3 | 1,153 | 1,374 | 809 | 886 |

The maximum dose readings* for an interventional radiologist were reported by the dosimetry provider as follows:

| | 2018 | 2019 | 2020 | YTD 9/30/2021 |
|---|---|---|---|---|
| DDE | 4,307 | 3,277 | 1,873 | 966 |
| LDE | 4,311 | 3,123 | 2,751 | 1,719 |
| SDE (whole body) | 4,176 | 3,021 | 2,717 | 1,980 |

*Note that these exposures trended down due to new fluoroscopy equipment with improved technology which provided lower exposure output and additional shielding to the physician, lowering personnel dose.

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 three radiologists.

Condition 13 of NRC License No. 13-02650-02 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 letters dated April 10, 2014.

Item 10, "Radiation Protection Program-Occupational Dose," of letter dated April 10, 2014, 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."

Because the licensee's earlier, undocumented evaluation was based on information from journal articles and a package insert and was not based on 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 concluded it was inadequate to demonstrate that dosimetry was not required. The licensee's failure to perform a prospective evaluation demonstrating that three 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 three interventional radiologists is a violation of License Condition 13.

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 radiologists 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 Y-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 three interventional radiologists authorized to use Y-90; (2) providing extremity monitoring to interventional radiologists who use Y-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.

### 3.3 Conclusions

The inspector identified two violations involving the licensee's failures to: (1) perform a prospective evaluation demonstrating that three 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 three 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 nuclear medicine staff working with or in the vicinity of licensed material. Through interviews, the inspector determined that the licensee staff understood radiation safety and 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 23, 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 October28, 2021, and included a discussion of the violations and the licensee's actions taken to restore compliance.

## LIST OF PERSONNEL CONTACTED

*Steve Baccam, CNMT
*#David Hofstra, BA, RT(N), CNMT, Administrative Director, Imaging & Therapy Divisions
*#Sharon Updike, MHP, DABR, Consultant Physicist, Medical Physics Consultants

Several nuclear medicine technologists were also contacted during this inspection

* Attended the on-site exit meeting on June 22, 2021
# Attended the October 28, 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