NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Saint Joseph Regional Medical Center 5215 Holy Cross Parkway Mishawaka, IN 46545 REPORT NUMBER(S) 2018001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-13685	13-02650-02	08/28-29/2018

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☒ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

1 Non-cited violation(s) were discussed involving the following requirement(s):

Contrary to Condition 13.A. of the license which references letter dated April 10, 2014, which contains application Section 8.24, Item 10, "Area Surveys", requiring the licensee to develop, implement, and maintain written procedures for area surveys, and licensee's written Procedure manual Item 25, requiring all areas where radioactive materials is handled, used, prepared, and stored are to be surveyed weekly for removable contamination, the licensee failed to conduct such weekly surveys between the period of April 13, 2018, and June 13, 2018. This violation is not being cited because it was self-identified, non-repetitive, and corrective action was taken. Specifically, the licensee identified and corrected this violation on June 13, 2018, with full compliance achieved on that date.

(Cont'd. on next page)

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Dennis P. O'Dowd	Dennis P. O'Dowd	08/29/18
BRANCH CHIEF	~~Geoffrey Warren, Acting~~ Aaron T. McCraw Chief		9/20/18

NRC FORM 591M PART 2
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Saint Joseph Regional Medical Center 5215 Holy Cross Parkway Mishawaka, IN 46545 REPORT NUMBER(S) 2018001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-13685	13-02650-02	08/28-29/2018

(Continued)

(Contd from Previous Page)

In its "Self-Identified Violation Report, signed by the RSO, the Technologist involved, and a management representative, the licensee identified the root cause of the violation as due to an oversight by the remaining staff member upon the retirement of the technologist who carried out this task at the end of the week (Friday), and the fact that the remaining staff Technologist did not work on Friday, the day the software calendar provided a notice that the task was due for completion. Staff were instructed on the need to carry out this task and ensure completion on a weekly basis. Note that this issue occurred at the licensee's facility at Saint Joseph Regional Medical Center, Plymouth Campus.

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Saint Joseph Regional Medical Center 5215 Holy Cross Parkway Mishawaka, IN 46545 REPORT NUMBER(S) 2018001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-13685	13-02650-02	August 28-29, 2018

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Sharon Updike, M.S., RSO	(517) 795-8786

☑ Main Office Inspection Next Inspection Date: 08/29/2020

☑ Field Office Inspection Med Ctr, Plymouth; PET Ctr, South Bend; and

☐ Temporary Job Site Inspection MBI Ctr, Mishawaka, all in Indiana

PROGRAM SCOPE

This was an unannounced, routine inspection of a 360-bed regional medical center authorized to use byproduct material for medical uses under 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.1000 at the licensee's main campus in Mishawaka, Indiana, uses under 35.100, 35.200, and 35.300 at the licensee's 55-bed regional medical center in Plymouth, IN, and 35.100, and 35.200 at the licensee's clinics in Mishawaka, Plymouth, and South Bend, IN. At the primary location, a staff of six nuclear medicine technologists (NMTs) conducted a full spectrum of diagnostic administrations using unit doses obtained from an area nuclear pharmacy. The licensee conducted approximately 15 administrations daily in addition to 1-2 administrations of I-131 requiring a written directive per month. The department performed nine Y-90 SIR-spheres treatments in 2017, and five (to date) in 2018. No Y-90 Theraspheres treatments have been performed since authorized. No manual brachytherapy treatments have been performed since April 2014. Two NMTs administered approximately 70 diagnostic administrations per month at the hospital in Plymouth. At the South Bend location one NMT performed 2-3 PET scans per day (Tuesday, Wednesday, and Thursday only). A Radiation Safety Committee reviewed the content and implementation of the program quarterly. The Radiation Safety Officer (RSO) for the license was an outside consultant who oversaw the radiation safety program, and conducted quarterly audits of the entire program.

PERFORMANCE OBSERVATIONS

The inspector toured the licensee's main facility and three additional locations of use to evaluate established measures for materials security, hazard communication, and exposure control. Independent and confirmatory surveys of these facilities found no readings indicative of residual contamination or exposures in excess of 10 CFR Part 20 dose limits. The inspector observed several diagnostic administrations at the main facility and one PET dose at the South Bend location. No therapeutic procedures involving licensed material uses were conducted during the time of the inspection. The inspector reviewed the licensee's protocols for Y-90 SIR-spheres, as demonstrated and described by staff, as well as the written directives, and other associated documentation. The inspector also reviewed a selection of Radiation Safety Committee meeting minutes, I -131 written directives with associated patient release calculations, survey records, calibration records and personnel dosimetry.

One Non-Cited Violation (NCV) of NRC requirements was documented as a result of this inspection.