

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Saint Joseph Regional Medical Center 5215 Holy Cross Parkway Mishawaka, IN 46545 REPORT NUMBER(S) 2016001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-13685	4. LICENSE NUMBER(S) 13-02650-02	5. DATE(S) OF INSPECTION September 22, 2016

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:

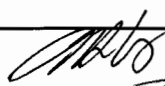
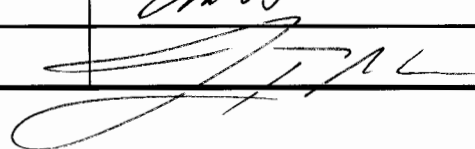
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

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

- 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	Luis Nieves Folch		9/22/2016
BRANCH CHIEF	Aaron T. McCraw		9/29/16

Docket File Information

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

1. PROGRAM CODE(S) 02240	2. PRIORITY 2	3. LICENSEE CONTACT Sharon Updike, MHP - RSO	4. TELEPHONE NUMBER (517) 795-8786
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- Main Office Inspection Next Inspection Date: September 22, 2018
- Field Office Inspection Plymouth, Indiana and South Bend, Indiana
- Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a 355-bed hospital authorized to use byproduct material for medical uses under 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.1000 at one location on the licensee Mishawaka, Indiana campus, and 35.100, 35.200, and 35.300 at the Plymouth facility and 35.100, and 35.200 at the South Bend, Indiana facility. At the primary location, a staff of five nuclear medicine technologists conducted a full spectrum of diagnostic administrations using unit doses obtained from an area nuclear pharmacy. The licensee conducted approximately 12 administrations daily in addition to 2-3 administrations of I-131 requiring a written directive per month. The department had performed six Y-90 SIR-spheres treatments since the last inspection and the radiation oncology department had performed no manual brachytherapy treatments since the last inspection. Two nuclear medicine technologists administered approximately 25 administrations per week at the locations in Plymouth, as well as 2-3 administrations of I-131 requiring a written directive per month. At the South Bend location one nuclear tech performs 3 PET scans a day only Tuesday, Wednesday, and Thursday. A Radiation Safety Committee reviewed the content and implementation of the program quarterly.

PERFORMANCE OBSERVATIONS

The inspector toured the licensee's main facility and two 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 the administration of one bone scan, eight Tc-99m cardiac stress test at both the main facility and Plymouth location and one PET dose at the South Bend location. The inspector reviewed the licensee's protocols for Y-90 SIR-spheres with an AMP, as well as the written directives, treatment plans, 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.

No violations of NRC requirements were identified as a result of this inspection.

Nieves Folch, Luis A

From: Nieves Folch, Luis A
Sent: Thursday, September 29, 2016 3:49 PM
To: 'supdike@mpcphysics.com'
Subject: FW: NRC 591 report
Attachments: image2016-09-29-162526.pdf

Dear Ms. Updike,

Attach is the clear 591 report for that inspection, no further actions are required at this moment on your part.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this message will be 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 me if you have any questions regarding this correspondence.

Thank you,

Luis Nieves
Health Physicist
U.S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
(630) 829-9571