

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

St. Joseph Health System LLC
d/b/a St. Joseph Hospital
700 Broadway
Fort Wayne, IN 46802

REPORT NUMBER(S) 2019001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-01581

4. LICENSE NUMBER(S)

13-00418-02

5. DATE(S) OF INSPECTION

October 21, 2019

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 | Edward F. Harvey | <i>Edward Harvey</i> | 10/21/2019 |
| BRANCH CHIEF | Robert Ruiz | <i>Robert J. Battone, Jr. for R-R.</i> | 10/30/2019 |

Docket File Information

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6. INSPECTION PROCEDURES USED

87131

7. INSPECTION FOCUS AREAS

All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02120

2. PRIORITY

3

3. LICENSEE CONTACT

Andre Stovall, MD, RSO

4. TELEPHONE NUMBER

(260) 425-3977

☒ Main Office Inspection

Next Inspection Date: October 21, 2022

☐ Field Office Inspection☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of a hospital authorized to possess and use unsealed byproduct material for diagnostic and therapeutic medical procedures at their location in Fort Wayne, Indiana. The licensee employed one full time nuclear medical technologist (NMT) who performed approximately three diagnostic procedures per day, Monday through Friday. Although authorized, the licensee had not performed any therapeutic administrations of unsealed byproduct material in the past two years. The licensee was also authorized to possess byproduct material permitted by 10 CFR 35.500 for storage incident to disposal; however, the inspector verified that the licensee did not possess any material under this authorization at the time of the inspection. The licensee retained the services of a medical physics consultant for instrument calibrations and quarterly program audits.

The inspector toured the licensee's facility in Mount Pleasant to evaluate the licensee's measures for material security, hazard communication, and exposure control. The inspector observed one diagnostic administration of licensed material for a gastric emptying study and noted that the NMT wore dosimetry and appropriate personal protective equipment, assayed the dose, and verified patient identity prior to the administration. The inspector observed the NMT demonstrate package receipt procedures, dose calibrator quality control, and area survey procedures. The NMT also demonstrated adequate knowledge of radiation protection principles and emergency procedures through interviews with the inspector.

The inspector reviewed a selection of licensee records, including quarterly audits, source inventories, survey meter calibration records, package receipt logs, written directives, and dosimetry with no issues noted. In addition, the inspector performed independent surveys, which revealed no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

No violations of NRC requirements were identified during this inspection.