

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

St. Joseph Mercy Health System

5301 E Huron River Dr.
Ann Arbor, MI 48106-0995

REPORT NUMBER(S) 2019001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-01997

4. LICENSE NUMBER(S)

21-00943-03

5. DATE(S) OF INSPECTION

March 14, 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	Zahid Sulaiman, Health Physicist	Zahid Sulaiman	3/14/19
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	ATM - for ATM	3/28/19

Docket File Information
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3. DOCKET NUMBER(S) 030-01997		4. LICENSE NUMBER(S) 21-00943-03	5. DATE(S) OF INSPECTION March 14, 2019
6. INSPECTION PROCEDURES USED 87131, 87132		7. INSPECTION FOCUS AREAS 03.01 - 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Joseph Wissing, RSO	4. TELEPHONE NUMBER (734) 712-8746
<input checked="" type="checkbox"/> Main Office Inspection		Next Inspection Date: <u>03/14/2021</u>	
<input checked="" type="checkbox"/> Field Office Inspection		<u>Michigan Heart, 5325 Elliot Dr, Ysiplanti, MI</u>	
<input type="checkbox"/> Temporary Job Site Inspection		<u>_____</u>	

PROGRAM SCOPE

This was a routine, unannounced inspection of a 537-bed hospital located in Ann Arbor, Michigan with authorization to use byproduct materials under 10 CFR Sections 35.100, 35.200, 35.300, 35.400, and 35.600 (iridium-192 in a high dose rate remote afterloader (HDR) system). The main hospital nuclear medicine department was staffed with five full-time, five part-time, and two PRN nuclear medicine technologists (NMTs). The NMTs typically administered approximately 300 diagnostic doses monthly, 25 iodine-131 (I-131 in capsules form) hyperthyroid and thyroid ablation, and 6 radium-223 therapy procedures annually. The diagnostic procedures included a variety of imaging and uptake procedures using technetium-99m (Tc-99m), primarily cardiac stress test, bone scan, HIDA, gastric emptying, lung scan using DTPA, and thyroid and hyperthyroid scans. The nuclear medicine department at Michigan Heart located at Ypsilanti, Michigan, was staffed with two full-time NMTs who performed approximately 200 cardiac stress test procedures monthly. The oncology department was staffed with seven oncologists, four authorized medical physicists (AMPs), and two dosimetrists who performed approximately 120 HDR gynecological and breast cancer treatments annually.

Performance Observations:

The inspection consisted of interviews with selected licensee personnel, a review of selected records, tours of the nuclear medicine departments, the oncology department, and independent measurements. The inspector observed a HDR gynecological cancer treatment procedure, and preparation and administration of Tc-99m to a patient. The inspector: (1) observed the NMT conduct a physical inventory of sealed sources, and all sources were accounted for; (2) had the NMT demonstrate the dose calibrator constancy check, package receiving and check-in procedures, the end of the day daily and weekly area surveys, and proper handling of radioactive waste and disposal procedures. The inspector had the AMP demonstrate the HDR unit's: (1) security, (2) daily spot checks, (3) emergency equipment and procedures, (4) safety procedures and instructions, (5) door interlock system, and (6) radiation monitoring equipment checks. The inspector also reviewed selected HDR and I-131 written directives and treatment plans. The inspector reviewed the following records: radiation safety committee minutes, quarterly program audits, DOT Hazmat training, linearity and accuracy of the dose calibrator, instrument calibration, package receipts, waste disposal records, radiation safety training, and sealed source leak tests and inventory.

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(Continued)

The inspector reviewed dosimetry records for 2017 through December 31, 2018, indicating the maximum annual dose to be 389 mrem - DDE, and 2,480 mrem - SDE. The inspector conducted independent and confirmatory radiation surveys and found no residual contamination or exposures to members of the public in excess of regulatory limits. The last HDR source was exchanged on February 20, 2019.

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