

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Beaumont Health System

3601 W. 13Mile Road
Royal Oak, MI 48073

REPORT NUMBER(S) 2018001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-02006

4. LICENSE NUMBER(S)

21-01333-01

5. DATE(S) OF INSPECTION

1/31/18 - 2/2/18

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	<i>Zahid Sulaiman</i>	2/2/18
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	<i>ATM</i>	2/23/18

Docket File Information

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3. DOCKET NUMBER(S) 030-02006	4. LICENSE NUMBER(S) 21-01333-01	5. DATE(S) OF INSPECTION January 31 - February 2, 2018	
6. INSPECTION PROCEDURES USED 87131, 87132, 87134	7. INSPECTION FOCUS AREAS 03.01 - 03.08		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 01100	2. PRIORITY 2	3. LICENSEE CONTACT Janice Campbell, Ph.D, RSO	4. TELEPHONE NUMBER (248) 551-0548
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☒ Main Office Inspection Next Inspection Date: 10/24/2019

☒ Field Office Inspection Troy, Sterling Heights, West Bloomfield Hills,

☐ Temporary Job Site Inspection Macomb, and Gross Pointe, Michigan

PROGRAM SCOPE

This was a routine, unannounced inspection of a medical broad-scope licensee authorized to use byproduct material for medical use and research at 10 locations specified on the license. During this inspection the main hospital's yttrium-90 (Y-90) and iodine-125 (I-125) eye plaque programs along with several authorized locations at Troy, Sterling Heights, West Bloomfield Hills, Macomb, and Gross Pointe, Michigan were inspected. The main hospital activities performed under 35.100, 35.200, 35.300, 35.400, 35.600 were inspected during the October 2017 inspection (IR2017001). At the main hospital, the licensee performed approximately 90 Y-90 and 10 I-125 eye plaque procedures annually.

The nuclear medicine department at Troy, MI was staffed with six full-time nuclear medicine technologist (NMTs). The licensee performed approximately 240 diagnostic nuclear medicine procedures monthly, primarily bone scan, cardiac stress tests, and HIDA scans. The licensee also performed approximately six Ra-223 Xofigo patient treatments quarterly. The oncology department was staffed with 3 oncologists, 4 medical physicists (AMPs), and 2 therapists who performed approximately 20 high dose-rate remote afterloader (HDR) brachytherapy treatments monthly. The HDR sources were exchanged quarterly, with the most recent exchange on November 27, 2017.

The West Bloomfield Hills nuclear medicine department was staffed with a full-time and a part-time NMT who performed approximately 200 diagnostic nuclear medicine procedures monthly, primarily bone scan, cardiac stress tests, HIDA, and thyroid scans. The licensee performed approximately 120 I-131 hyperthyroidism and ablations procedures annually.

The Macomb, MI, nuclear medicine department employed two full-time NMTs and one full-time aide who performed approximately 120 diagnostic nuclear medicine procedures monthly, mostly cardiac stress tests, bone scan, gastric emptying and HIDA scans.

The mobile PET at Sterling Heights, MI was staffed with three full-time NMTs who performed approximately 200 F-18 unit dose PET diagnostic procedures monthly. The mobile PET clinic operated from Monday through Thursday.

Continued on next page.

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(Continued)

The Gross Pointe, MI nuclear medicine department was staffed with eight full-time NMTs who performed approximately 350 full spectrum diagnostic procedures monthly and 9 I-131 in capsule form for hyperthyroidism treatments annually.

PERFORMANCE OBSERVATIONS

The inspection consisted of interviews with select licensee personnel; a review of select records; and tours of the nuclear medicine department, oncology department, interventional radiology suite, and various Beaumont Hospital locations (Troy, Sterling Heights, West Bloomfield Hills, Macomb, and Gross Pointe, MI). The inspector observed the preparation and administration of F-18 and Tc-99m for diagnostic procedures and one HDR gynecological cylinder treatment to a patient.

The inspector: (1) observed the NMT and AMP conduct a physical inventory of sealed sources, and all sources were accounted for; (2) had the NMT demonstrate the dose calibrator constancy check, the end of the day daily area surveys and weekly wipe tests, 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. The inspector also reviewed the HDR (prostate, gynecological, and breast cancer treatments), Y-90 microspheres, and I-131 written directives and treatment plans.

The inspector reviewed the following records: radiation safety committee minutes, quarterly and annual program audits, package receipts, waste disposal records, DOT Hazmat training, linearity and accuracy of the dose calibrator, instrument calibration, daily area surveys and weekly wipe tests, and sealed source leak tests. The inspector conducted independent and confirmatory surveys and found no residual contamination or exposures to members of the public in excess of regulatory limits.

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