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
Beaumont Health System 3601 W. 13Mile Road Royal Oak, MI 48073 REPORT NUMBER(S) 2017001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02006	21-01333-01	October 24-26, 2017

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.

_____ 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	11/17/17
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		11/27/17

NRC FORM 591M PART 3
(07-2012)
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U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87137	03.01 - 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02120	2	Cheryl Culver Schultz, RSO	(248) 551-0548

☑ Main Office Inspection Next Inspection Date: 10/24/2019

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

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. The main hospital in Royal Oak, MI, a 1,100-bed hospital, performed activities under 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000. During this inspection only the main hospital activities were inspected with the exception of the yittrium-90 (Y-90) program, which was not reviewed. The licensee employed 30 nuclear medicine technologists (NMTs) working in three nuclear medicine areas within the hospital including a main nuclear medicine area, a PET area, and a cardiology clinic on the 8th floor. The licensee possessed a molybdenum-99 (Mo-99) generator to prepare technetium-99m (Tc-99m) doses for pediatric renal scans. The licensee received a Mo-99 generator every Sunday morning. The licensee also received unit doses, bulk Tc-99m, and iodine-131 (I-131) in solution form from a licensed radiopharmacy. The main nuclear medicine area administered approximately 1,900 doses, 28 1-131 therapy procedures, 8 Y-90 microspheres, and 1 radium-223 therapies monthly. The cardiology clinic on the 8th floor performed approximately 75 cardiac stress tests per week. The licensee received PET doses via direct pneumatic transfer tube from a commercial cyclotron operating in the main hospital.

The oncology department was staffed with 15 oncologists, 6 medical physicists, and 5 dosimetrists. The oncology activities at the main hospital included high dose-rate remote afterloader (HDR) brachytherapy (around 20 fractions monthly), intravascular brachytherapy (IVB) (around 8 procedures monthly using a Sr-90 source train), and iodine-125 eye plaques (around 10 procedures annually).

PERFORMANCE OBSERVATIONS

The inspection consisted of interviews with select licensee personnel; a review of select records; and tours of the nuclear medicine, oncology department, 8th floor cardiology clinic, and long-term decay in storage facility. The inspector observed the administration of Tc-99m doses to a patient for a cardiac stress test and two HDR treatments (prostate and breast cancer procedures), and the elution and preparation of Tc-99m dosages from the Mo-99 generator. The inspector: (1) observed the NMT and AMP conduct a physical inventory of sealed sources, and all sources were accounted for; (2) had the authorized nuclear pharmacist (ANP) demonstrate Mo-99 generator elution and checks, kit preparation, QC, kit labeling and tracking; (3) had the ANP 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.

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NRC FORM 591M PART 2
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(Continued)

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 reviewed the HDR (prostate and breast cancer treatments), and the IVB 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 reviewed the dosimetry records for 2015 through September 30, 2017 which indicated the maximum annual dose to be 1,142 mrem - DDE; and 16,668 mrem - SDE. The inspector also reviewed eight fetal dose records since the last inspection, and doses were within the regulatory limits. 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.