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 West 13 Mile Road Royal Oak, MI 48073 REPORT NUMBER(S) 2019001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02006	21-01333-01	09/23/19 - 10/02/19

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.

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

Contrary to 10 CFR 35.63(d), Beaumont Health System identified that on June 21, 2018, it used a 58.4-millicurie dosage of Tc-99m that fell outside of the prescribed dosage range of 10 to 20 millicuries for a white blood cell tagging study.

As corrective action, the licensee performed a dose evaluation, retrained staff, revised its protocol for this study, and worked with the commercial radiopharmacy who supplied the dose to develop additional corrective actions there to address the potential for recurrence.

☐ 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	Ryan Craffey	Ryan Craffey	10/2/19
BRANCH CHIEF	Robert Ruiz, Acting Chief	Michael Runyan for	10/16/19

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132, 87134	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
04710	2	Sheila Shaffer, MS - RSO	(248) 551-1086

☑ Main Office Inspection Next Inspection Date: 09/23/2021

☑ Field Office Inspection Various - See Below

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a broad-scope medical and research institution authorized to use byproduct material for medical diagnosis, therapy, and research at its main campus in Royal Oak, Michigan, and at numerous satellite facilities in the northern metro Detroit area. The licensee operated a non-commercial radiopharmacy at Beaumont Hospital - Royal Oak to prepare unit doses of Tc-99m from Mo/Tc generators. The hospital also received unit doses of F-18 and N-13 via pneumatic tube from an on-site cyclotron operated by PETNET under separate NRC licenses (41-32729-05MD and -06). The licensee operated two nuclear medicine departments at the main campus in Royal Oak, and one at each satellite facility, with the exception of St. Clair Shores, where licensed activities were limited to mobile PET on Fridays Saturdays, and Sundays (the trailer was at the Sterling Heights facility all other days). The licensee routinely administered liquid I-131 and Ra-223 dichloride for therapeutic purposes at Royal Oak and Sterling Heights, as well as Y-90 microspheres at Royal Oak. The licensee operated radiation oncology departments at Royal Oak and Troy. Both departments performed HDR brachytherapy (primarily prostate and gynecological), as well as occasional I-125 eye plaque and Sr-90 intravascular LDR brachytherapy at Royal Oak. Research activities were limited to occasional animal imaging studies at the Research Institute's microPET/CT lab, using hand-delivered F-18 doses from PETNET. The licensee's RSO oversaw the program with assistance from radiation safety staff and other designated individuals who audited each department quarterly. The licensee's RSC met quarterly to review and approve users and uses under the license, monitor occupational exposure trends, and evaluate program changes and variances.

PERFORMANCE OBSERVATIONS

The inspector toured Beaumont Hospital - Royal Oak, Beaumont Research Institute in Royal Oak, Beaumont Hospital - Troy, Outpatient Services Center - Sterling Heights, Beaumont Health Center on Coolidge Highway in Royal Oak, Beaumont Medical Center - Lake Orion, and St. Clair Shores Family Medicine Center to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector performed independent and confirmatory surveys throughout each of these facilities, and found no evidence of residual contamination or exposures in excess of regulatory limits to members of the public.

[Continued on Part 2.1]

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(Continued)

The inspector observed an HDR prostate treatment, an HDR vaginal cylinder treatment, a Y-90 microspheres administration, more than a dozen diagnostic administrations of Tc-99m, F-18, and N-13 radiopharmaceuticals, dose drawing and preparation at the licensee's radiopharmacy, and receipt of packages containing licensed material. The inspector also observed demonstrations of intravascular brachytherapy (IVB) treatment delivery, liquid I-131 preparation and administration, preparation and use of material for animal imaging studies, and the implementation of procedures for area surveys, contamination control, and radioactive waste handling. The inspector also verified select sealed source inventories and interviewed numerous staff and management, including authorized users, the licensee's authorized nuclear pharmacist, and radiation safety staff to discuss the status and oversight of the program and implementation of radiation safety procedures and ALARA practices.

The inspector reviewed a selection of written directives and treatment planning and verification documentation for HDR, Y-90 microspheres, liquid I-131 and Ra-223 dichloride administrations. These records provided high confidence that such administrations had been performed in accordance with written directives. The inspector also reviewed a selection of HDR spot checks and full calibrations, documentation of HDR emergency training, I-131 patient release calculations, thyroid bioassay results, air effluent monitoring calculations, routine nuclear medicine records including various surveys and instrument quality control checks, quarterly department audits, RSC meeting minutes including variance reports, and personnel dosimetry reports, which indicated that occupational exposures from activities conducted under this license were below regulatory limits.

During a review of variance reports, the inspector noted that the licensee had identified a violation of 10 CFR 35.63(d) for using a dosage of Tc-99m in a white blood cell tagging study that did not fall within the prescribed dosage range. Specifically, on June 21, 2018, the licensee administered 58.4 millicuries of Tc-99m when the prescribed range for the study was only 10 to 20 millicuries, and had not otherwise been directed by an authorized user to do so. The root cause of the violation was an oversight by the technologist administering the dose. As a contributing factors, neither the staff at the hospital nor the staff at the commercial radiopharmacy where the blood was tagged had expected the isotope to bind as well as it did; yields almost always fell within the prescribed dose range. Moreover, the licensee does not routinely double-check these doses in a dose calibrator prior to administration, due to biohazard safety concerns and the need to work quickly once the blood is returned from the radiopharmacy. As corrective action, the licensee performed a dose evaluation to confirm that this administration did not result in a medical event, revised its protocol for this study to more explicitly identify the prescribed dosage range and to include a requirement to report any dose received over 30 millicuries, retrained staff on the revised policy; and worked with the radiopharmacy who supplied the dose to develop additional corrective actions for their program, such as more explicitly identifying the 30-millicurie limit in their polices and on postings in areas where blood products were handled.

Since this violation was self-identified, non-repetitive, non-willful, and since corrective action had already been taken to restore compliance and address the potential for recurrence, the NRC characterized the violation as an NCV.

[Continued on Part 2.2]

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The inspector also noted during a review of variance reports that the licensee had experienced two incidents involving the device used to perform IVB treatments. In October 2018, following a successful treatment, the licensee removed the treatment catheter from the device after dropping it while investigating a fluid leak and in doing so inadvertently removed the Sr-90 source train from the device. Shortly thereafter, in January 2019 the licensee was unable to return the source train to its shielded position in the device after aborting a treatment (no dose was delivered) due to an obstruction in the treatment catheter. In both instances redundant equipment was immediately available to perform all required safety functions (i.e. shielding the source train), and in both instances personnel exposures appeared to be minimal. In response to both incidents, the licensee returned the device to the manufacturer. The manufacturer repaired the device after the first incident, then replaced it after the second. The licensee also revised its protocol for IVB treatments to include additional steps for minimizing the likelihood of inadvertently creating obstructions in the treatment catheter.

The inspector determined that neither incident was reportable, and that neither involved a violation of regulatory requirements. However, the next inspector should consider placing special emphasis on IVB treatments and staff involved in them to continue evaluating the licensee's ongoing efforts to minimize the potential of future incidents involving the device.