NRC FORM 591M
(04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Report

1. Licensee/Location Inspected:	2. NRC/Regional Office
Beaumont Health System 3601 W 13 Mile Rd. Royal Oak, MI 48073 Report Number(s) 2022001	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	08/08/2022-10/18/2022

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
(Non-cited violation(s) was/were discussed involving the following requirement(s)

B. The following violation(s) is/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)

A. 10 CFR 20.1906(d) requires, in part, that licensees immediately notify the final delivery carrier and the NRC Headquarters Operations Center by telephone when removable radioactive surface...

(continued on next page)

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 AND DATE
LICENSEE'S REPRESENTATIVE	Debra Guido-Allen	Debra A. Guido Allen
NRC INSPECTOR	E. Tindle-Engelmann, L. Nieves Folch	Elizabeth D. Tindle-Engelmann Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2022.10.19 07:02:31 -05'00'
BRANCH CHIEF	Michael A. Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.10.19 06:51:48 -05'00'

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...contamination exceeds the limits of 10 CFR 71.87(i).

Contrary to the above, on April 12, 2022, the licensee failed to immediately notify the NRC Headquarters Operations Center by telephone when removable radioactive surface contamination exceeded the limits of 10 CFR 71.87(i). Specifically, upon receipt of a package containing iodine-131 with a non-fixed contamination level greater than 240 disintegrations per minute per centimeter squared the licensee only notified the final delivery carrier of the excessive removable radioactive surface contamination.

Upon identification of the failure on August 9, 2022, the licensee notified the NRC Headquarters Operations Center by telephone of the excessive removable radioactive surface contamination. EN 56038 / NMED 220347 (closed) was assigned. In order to prevent recurrence, the licensee reviewed and updated applicable training materials, policies, and protocols related to package receipt with an emphasis on reporting requirements.

B. 10 CFR 35.24(f) requires, in part, that the membership of the Radiation Safety Committee include an authorized user of each type of use permitted by the license, a Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor the Radiation Safety Officer.

Contrary to the above, from June 21, 2021, to August 8, 2022, the licensee failed to include an authorized user of each type of use permitted by the license on the Radiation Safety Committee. Specifically, the licensee was permitted for the use of yttrium-90 under 10 CFR 35.1000 but the licensee failed to include an authorized user of 10 CFR 35.1000 yttrium-90 on the Radiation Safety Committee during the aforementioned time period.

Upon identification of the issue, the licensee requested that a yttrium-90 authorized user join the Radiation Safety Committee. A yttrium-90 authorized user had accepted membership on the Radiation Safety Committee and was formally approved as a member of the Radiation Safety Committee in September of 2022.

C. 10 CFR 20.1502(a)(1) requires, in part, that each licensee monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, for periods between October of 2019 and August of 2022, the licensee failed to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and did not require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii). Specifically, five authorized users of yttrium-90, whose occupational exposure to licensed and unlicensed sources of radiation was likely to exceed 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii), often failed to wear their supplied extremity dosimeter, thereby preventing the licensee from monitoring their occupational shallow-dose equivalent exposure to the skin of the whole body or the skin of the extremity.

Upon identification of the violation, the licensee determined that the individuals were likely to receive a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii) but were unlikely to exceed the occupational limit. As a corrective action, the licensee provided remedial training to the individuals on the proper use of extremity dosimeters and revised their radiation badge policy to clarify requirements for the use of extremity monitors.

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Beaumont Health System	030-02006	21-01333-01

4. Report Number(s):	5. Date(s) of Inspection:
2022001	08/08/2022-10/18/2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Elizabeth D. Tindle-Engelmann, Luis Nieves Folch	04710	2	87130, 87132, 87134

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Sheila Shaffer, RSO	Sheila.Shaffer@beaumont.org	248-551-1086

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced	☑ Main Office ☑ Field Office ☐ Temporary Job Site ☐ Remote	08/08/2024 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced routine inspection. The licensee was a broad scope medical facility located in Royal Oak, Michigan, with satellite facilities across the Detroit metro area. The licensee was authorized for a wide range of byproduct material for diagnostic, therapeutic, and research uses including multiple remote afterloader units pursuant to 10 CFR 35.600, yttrium-90 microspheres pursuant to 10 CFR 35.1000, and depleted uranium for shielding in a non-commercial radiopharmacy. The licensee's radiation safety officer (RSO) was a full-time employee who was onsite daily and had support of two Associate RSOs and multiple physicists. The RSO's team was responsible for program reviews, equipment calibrations, program audits, and oversight of the radiation protection program. The licensee maintained a radiation safety committee that met quarterly.

The Royal Oak hospital had an active non-commercial radiopharmacy, nuclear medicine department, nuclear cardiology department, PET department, radiation oncology department, and yttrium-90 microsphere program. The radiopharmacy compounded unit doses of technetium-99m and received one molybdenum-99/technetium-99m generator per week. Doses of radiopharmaceuticals with fluorine-18, gallium-68, iodine-123, iodine-131, radium-223, and copper-64 were obtained as needed from a commercial radiopharmacy. The Sterling Heights/Troy hospital had an active nuclear medicine department, nuclear cardiology department, PET department, and radiation oncology department. Both radiation oncology departments had a high dose rate remote afterloader and actively performed prostate and gynecological treatments. The radiation oncology group was also responsible for iodine-125 eye plaque treatments and strontium-90 intravascular brachytherapy. The licensee's other facilities each had lower volume nuclear medicine departments.

Since the last inspection, the licensee had not performed any research activities and they had decommissioned multiple areas that had previously been used for research.

Observations

The inspectors toured the Royal Oak, Sterling Heights, Troy, Macomb, and Grosse Pointe authorized locations. The inspectors observed the administration of multiple high dose rate remote afterloader brachytherapy treatments, ambient radiation level surveys, decay in storage procedures, dose calibrator quality control, dose preparation and administration, package receipt procedures, preparation and administration of yttrium-90 microspheres, radiopharmacy operations including unit dose compounding, remote afterloader spot checks, and sealed source inventories. Interviews with licensee personnel indicated adequate knowledge of radiation safety and security

Materials Inspection Record (Continued)

concepts and procedures. The licensee's management, including the Chief Operating Officer and the Radiation Safety Committee Chair, actively participated in the management oversight of the radiation protection program. The inspectors reviewed the following records related to the broad scope license: approvals of individuals including authorized users and authorized medical physicists, approvals of radiation safety protocols, approvals of new facilities within authorized locations, facility decommissioning records, radiation safety committee meeting minutes, radiation safety variance reports, and select policies and procedures. The inspectors reviewed the following records related to the use of licensed material: area surveys, dose calibrator calibrations, dosimetry, HDR spot checks, HDR full calibrations, package receipt, package return, program reviews, radionuclide breakthrough testing, sealed source leak tests and inventories, spill reports, training, treatment plans, waste logs, and written directives.

The inspectors performed independent and confirmatory radiation measurements using a RadEye G (serial number: 30337, calibration expiration: 03/29/2023).

During a review of the licensee's internal incident (variance) reports, the inspectors observed that the licensee had experienced multiple incidents involving the device used to perform strontium-90 intravascular brachytherapy treatments. All the incidents involved the licensee's inability to return the source train to its shielded position within the device because of an obstruction in the treatment catheter. On all occasions, the emergency response equipment was available and the emergency procedures were followed to safely place the source in an external shield. No occupational overexposures or medical events occurred based on these incidents. The licensee contacted the device manufacturer for an investigation. The manufacturer provided guidance on preventing catheter obstructions. The licensee incorporated this guidance into its procedures.

During the non-commercial radiopharmacy inspection, the NRC was made aware of a contaminated package that was received by the licensee on April 12, 2022. The package contained iodine-131 and had a non-fixed contamination level of approximately 300 disintegrations per minute per centimeter squared which is above the limit of 240 disintegrations per minute per centimeter squared, as specified in 10 CFR 71.87(i), and ultimately in 49 CFR 173.443. Upon identification of the contamination, the licensee notified the final delivery carrier of the excessive removable radioactive surface contamination. The package was isolated and stored for decay. No contamination was identified in the facility. However, the licensee failed to immediately notify the NRC Headquarters Operations Center by telephone when the removable radioactive surface contamination exceeded the limits; this is a violation 10 CFR 20.1906(d). Upon identification of the failure on August 9, 2022, the licensee notified the NRC Headquarters Operations Center by telephone of the excessive removable radioactive surface contamination. EN 56038 / NMED 220347 was assigned and was reviewed during the inspection. The NRC considers its review of this event closed. In order to prevent recurrence, the licensee reviewed and updated applicable training materials, policies, and protocols related to package receipt with an emphasis on reporting requirements.

During review of the RSC meeting minutes, the inspectors determined that the licensee has a radiation safety committee that meets quarterly. However, the licensee's RSC membership does not meet the requirements set forth in 10 CFR 35.24(f). Specifically, the licensee was permitted for the use of yttrium-90 under 10 CFR 35.1000 but the licensee failed to include an authorized user of 10 CFR 35.1000 yttrium-90 on the Radiation Safety Committee from June 21, 2021, to August 8, 2022. Upon identification of the issue the licensee requested that a yttrium-90 authorized user join the Radiation Safety Committee. A yttrium-90 authorized user accepted membership on the Radiation Safety Committee and was formally approved as a member of the Radiation Safety Committee in September of 2022.

During a review of the dosimetry records, the inspectors observed that five authorized users of yttrium-90 whose occupational exposure to licensed and unlicensed sources of radiation was likely to exceed 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii) often failed to wear their supplied extremity dosimeters. The inspectors confirmed that the licensee provided the individual extremity dosimetry based on their likelihood to exceed 10 percent of the limits in 10

Materials Inspection Record (Continued)

CFR 20.1201(a)(2)(ii). The failure of the individuals to wear the monitoring devices prevented the licensee from monitoring their occupational shallow-dose equivalent exposure to the skin of the whole body or the skin of the extremity which is a violation of 10 CFR 20.1502(a)(1). Upon identification of the violation, the licensee determined the individuals were unlikely to exceed the occupational limit through review of whole body dosimetry, review of caseload, and interviews regarding work practices. The licensee estimated the extremity dose for each of the individuals for the years 2016-2021. On average, each individual received approximately 15 rem to the extremity per year. The maximum estimated extremity dose to any individual in a single year was 32.7 rem and the minimum was 4.5 rem. As a corrective action, the licensee provided remedial training to the individuals on the proper use of extremity dosimeters and revised their radiation badge policy to clarify the requirements for the use of extremity monitors.

Three severity level IV violations were identified as a result of this inspection [10 CFR 20.1906(d), 10 CFR 35.24(f), 10 CFR 20.1502(a)(1)]. EN 56038 / NMED 220347 is closed.