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
Spectrum Health Hospitals 100 Michigan St. NE Grand Rapids, Ml 49503 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
070-01486	SNM-1432	July 5-7, 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. 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 M. Sulaiman Digitally signed by Zahid M. Sulaiman Date: 2022.07.29 18:11:25 -05'00'	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.08.01 14:18:04 -05'00'	

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Spectrum Health Hospitals	030-01989	21-00243-06

4. Report Number(s):	5. Date(s) of Inspection:
2022001	July 5-7, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Zahid Sulaiman, Health Physicist	02230	2	87131 & 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Evan Boote, PhD., RSO	evan.boote@spectrumhealth.org	Work: (616) 391-2498 Cell: (573) 424-6905

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	07/05/2024 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

This was a routine, unannounced, inspection. The licensee operated two major hospitals, a cancer center, and additional facilities in Grand Rapids, Michigan, and nuclear medicine or cardiology clinics at several hospitals in the region, as described on the license. The licensee was authorized to use byproduct materials under 10 CFR Sections 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 (Iridium-192, high dose rate (HDR) remote afterloader), and 35.1000 (yttrium-90 (Y-90) microspheres and iodine-125 seeds implants to localize non-palpable lesions). Nuclear medicine technologists (NMTs) rotated between licensed sites as needed. Facilities inspected included Butterworth Hospital, 100 Michigan St. NE, Grand Rapids, MI; Lemmen-Holton Cancer Pavilion, 145 Michigan St. NE, Grand Rapids, MI; Blodgett Hospital, 1840 Wealthy St. SE, Grand Rapids MI. Licensee closed the Reed City and West Pavilion facilities and transferred the sources to other location of use. Licensee will submit an amendment request to add two ARSO into the license.

At Butterworth Hospital, the licensee performed nuclear medicine out of two areas: main nuclear medicine and cardiology clinic. Main nuclear medicine technologists assisted surgical staff in around 20 microspheres therapy procedures quarterly. NMTs performed approximately 25 iodine-131 (I-131) hyperthroid and thyroid ablation procedures annually. In addition, the licensee operated a positron emission tomography (PET) clinic where five technologists performed around 17 procedures daily including cancer and brain imaging using F-18 FDG unit doses and cardiac imaging using Rb-82. The licensee possessed a RUBY-FILL rubidium-82 generator and elution system; the rubidium generator are changed every 6 weeks. At Blodgett Hospital, licensee performed approximately 30 radium-223 (Xofigo) and 8-10 I-131 therapy procedures annually.

The Cancer center was staffed with nine oncologists, seven authorized medical physicists (AMPs), and several dosimetrists who performed approximately 30 permanent prostate implants using mostly I-125 and Pd-103 seeds, 60 HDR (gynecological) brachytherapy procedures, and 12 temporary eye plaques using I-125 seeds annually. Licensee has not performed temporary seed implants using Cs-137 (since January 2019), the localize non-palpable lesions using I-125 seeds (since December 2020), and the ophthalmic radiotherapy using Sr-90 sealed sources (kept for storage only).

PERFORMANCE OBSERVATIONS

This inspection consisted of a tour of the hospitals, cancer center, nuclear medicine department; interviews with select licensee personnel; a review of select records; an observation of security of the materials; and independent measurements. The inspector had an NMT and an AMP conduct a physical inventory of sealed sources, and all

Materials Inspection Record (Continued)

sources were accounted for. The inspector had the NMT demonstrate the dose calibrator constancy check, package receipt procedures, the end of the day daily and weekly area surveys, proper handling of radioactive waste and disposal procedures, with no issue noted. The inspector observed the licensee staff prepare and administer several diagnostic dosages. The inspector had the NMT demonstrate the preparation and assay of a Y-90 microspheres dosage. The inspector also had the NMT demonstrate the Rb-82 generator elution and breakthrough calculation. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. Through these observations, demonstrations, and other discussions, the inspector found that the licensee personnel were knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

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; (6) radiation monitoring equipment checks; and (7) full calibration measurement. The inspector reviewed select HDR, manual brachytherapy prostate seeds implant, Y-90, I-131, Sr-90 eye plaque, and Ra-223 written directives, treatment plans, and patient release calculations for therapeutic administrations and found no issues.

The inspector reviewed the following records: radiation safety committee minutes, quarterly program audits, package receipts, waste disposal records, DOT hazmat training, constancy, linearity, and accuracy tests of the dose calibrator, sealed source leak tests and inventory, daily area surveys, and weekly wipe tests. The inspector reviewed the dosimetry records for 2020 through June 30, 2022, indicating the maximum annual dose to be 487 mrem - DDE, and 2,439 mrem - SDE. The inspector also reviewed two declared pregnancy fetal monitoring reports and the results were within the regulatory limits.

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