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 Street NE Grand Rapids, Michigan 49503 REPORT NUMBER(S) 2015-001	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
030-01989	21-00243-06	May 21 thru 21, 2015 18-21

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)

Contrary to 10 CFR 35.643(a) and (d)(6), as of May 19, 2015, the licensee failed to perform adequate spot checks of a high dose-rate (HDR) remote afterloader unit ~~in that the spot~~ before the first use of the HDR unit on a given day in that the spot checks did not assure timer accuracy. The root cause ~~to~~ of the violation was that the licensee was unaware of the requirement. As corrective action, the licensee committed to revising the HDR quality assurance procedure and checklist, train all personnel who perform the daily spot checks on the HDR unit, and begin performing the timer accuracy check no later than May 29, 2015.

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	Larry Gonzink Adm Dir.		5/21/15
NRC INSPECTOR	Geoffrey M. Warren		5/21/15
BRANCH CHIEF	Aaron T. McCraw		5/29/15

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Spectrum Health Hospitals 100 Michigan Street NE Grand Rapids, Michigan 49503 REPORT NUMBER(S) 2015-001	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
030-01989	21-00243-06	May 18-21, 2015

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132	03.01 - 03.08; 03.01 - 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Evan Boote, Ph.D., RSO	(616) 391-2498

☑ Main Office Inspection Next Inspection Date: May 2017

☑ Field Office Inspection See Below

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced, inspection. The licensee operated two major hospitals, a cancer center, and additional facilities in Grand Rapids, Michigan, and cardiology clinics at several area hospitals, as described on the license. The license authorized diagnostic and therapeutic nuclear medicine, brachytherapy using a variety of isotopes, a high dose rate (HDR) remote afterloader using Ir-192, microspheres treatments using Y-90, and I-125 seeds for localication of non-palpable lesions. Nuclear medicine technologists rotated between sites under the license 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; Building 35, 35 Michigan St. NE, Grand Rapids, MI; 8333 Felch St., Zeeland, MI; and 602 Michigan Ave., Holland, MI.

At Butterworth Hospital, the licensee performed nuclear medicine out of two areas: main nuclear medicine and cardiology. At main nuclear medicine, three technologists performed a variety of procedures totaling approximately 300 diagnostic procedures monthly, with doses received as unit doses or prepared from bulk technetium. They also performed around 20 I-131 therapy procedures and 12 Ra-223 therapy procedures quarterly, and assisted in around 20 microspheres therapy procedures quarterly, performed in surgery. In the cardiology area, two technologists performed approximately 320 cardiac rest and stress procedures monthly using unit doses. Cancer center staff performed temporary seed implants using Cs-137 seeds and permanent prostate implants using Pd-103 and I-125 seeds at this hospital; records were maintained at the cancer center.

At the cancer center, the licensee operated an HDR unit, performing approximately 200 treatment fractions quarterly, primarily breast and GYN procedures. In addition, the licensee operated a positron emission tomography (PET) clinic where four technologists performed around 250 procedures monthly, including cancer and epilepsy imaging using F-18 FDG unit doses. Surgical staff implanted around 100 I-125 seeds annually into non palpable breast lesions; these were removed in surgery at Butterworth Hospital and taken to main nuclear medicine there for decay in storage.

At the Building 35 facility, the licensee operated a pathology laboratory where breast tissue was analyzed; some of this tissue contained residual Tc-99m from sentinel lymph node procedures.

(Continued on Part 2)

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Spectrum Health Hospitals 100 Michigan Street NE Grand Rapids, Michigan 49503 REPORT NUMBER(S) 2015-001	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
030-01989	21-00243-06	May 18-21, 2015

(Continued)

The facility in Holland, Michigan, was a cardiology clinic on the campus of Holland Hospital. One technologist performed approximately 120 cardiology procedures monthly. Doses were received as unit doses.

The facility in Zeeland, Michigan, was a cardiology clinic on the campus of Zeeland Community Hospital. One technologist performed approximately 40 cardiology procedures monthly, primarily on Mondays, Tuesdays, and Fridays. In addition, hospital personnel performed one sentinel node procedure monthly under this license. All doses were received as unit doses.

At Blodgett Hospital, the licensee performed diagnostic and therapeutic nuclear medicine procedures and implanted and explanted I-125 seeds in non-palpable lesions. Helen DeVos Children's Hospital included a diagnostic and therapeutic nuclear medicine facility. The Bradford Street facility in Grand Rapids and the facility in Wyoming, Michigan were cardiology clinics similar to the facilities in Holland and Zeeland. At the Lake Drive Surgery Center, licensee personnel performed sentinel lymph node procedures, removed lymph samples, and had them couriered to Butterworth Hospital for analysis.

Performance Observations: The inspectors observed one HDR procedure, eight diagnostic nuclear medicine procedures, checkout of I-125 seeds for breast implant, package receipt surveys, daily nuclear medicine checks, and identification and handling of contaminated linens. Licensee personnel demonstrated daily HDR checks, seed inventory, and daily and weekly contamination surveys, and described radiopharmaceutical therapy procedures, microspheres treatments, temporary and permanent seed implant procedures, handling of tissue samples with residual radioactive material, and auditing procedures. The inspectors noted no concerns with these procedures except as described below. The inspectors reviewed written directives for each therapy modality and found no issues. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of regulatory concern. The inspectors performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The inspectors identified one violation concerning the licensee's failure to perform timer accuracy testing as part of the daily checks for the HDR unit, as described on Part 1 of this form. The licensee was performing the checks as described in their written procedure and documenting them on their checklist; neither the procedure nor the checklist included this test.