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
Edward W. Sparrow Hospital 1215 East Michigan Avenue Lansing, MI 48909 REPORT NUMBER(S) 2018001	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
030-02009	21-01430-01	June 21-22, 2018

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	Ryan Craffey	Ryf Craffey	6/22/18
BRANCH CHIEF	Aaron McCraw		07/02/2018

NRC FORM 591M PART 3
(07-2012)
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Docket File Information

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

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Martin Johnson, MS - RSO	(517) 364-2167

☑ Main Office Inspection Next Inspection Date: 06/21/2020

☑ Field Office Inspection 1140 & 1215 E Michigan (PET & HDR Suites)

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a regional health system authorized to use byproduct material for diagnostic and therapeutic medical purposes at its campus in downtown Lansing, Michigan, and at satellite facilities in St. Johns, Carson City, and Ionia. At the Herbert-Herman Cancer Center (1140 E Michigan), the licensee operated its HDR unit on a near-daily basis to perform breast and gynecological treatments, and performed occasional I-131 administrations for thyroid carcinoma. At the main hospital (1215 E Michigan), the licensee's primary hot lab performed around a dozen diagnostic administrations per day (excluding cardiac stress tests) on one of two shifts, and occasional I-131 administrations for TMS scans and hyperthyroidism. The licensee performed cardiac stress tests at a second department in the Heart and Vascular Center (also at 1215 E Michigan), and PET scans using an automated infusion system at a third department adjacent to the primary one. At the 1200 E Michigan address, the licensee performed occasional lymphoscintigraphy studies, and at each of the three satellite facilities performed diagnostic administrations only. The licensee had also performed four Y-90 microsphere administrations since the last inspection, one I-125 prostate seed implant, and continued to utilize a self-shielded irradiator in the processing of blood products.

PEFORMANCE OBSERVATIONS

The inspector toured various facilities at the downtown campus in Lansing to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector observed two fractions of an HDR treatment, and several diagnostic administrations at the main hospital's primary and PET departments. The inspector noted that the Cancer Center and PET suite, added to the license since the last inspection, matched the description provided by the license in its request dated June 6, 2017. The inspector conducted independent surveys of these facilities, including at the disused cancer center at 1215 E Michigan with an NaI scintillation probe, and found no evidence of residual contamination or exposures to members of the public in excess of regulatory limits. The inspector interviewed various members of the licensee's staff to discuss procedures for the use of licensed material, ALARA practices, and oversight of the radiation safety program. The inspector found these individuals to be knowledgeable of radiation protection principles and regulatory requirements.

[continued on Part 2]

NRC FORM 591M PART 2
(07-2012)
10 CFR 2.201

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(Continued)

The inspector reviewed written directives and planning and verification documentation for a selection of HDR treatments and I-131 administrations, as well as for all manual brachytherapy and microsphere treatments since the last inspection. The inspector found that the licensee's procedures provided high confidence that such treatments were performed in accordance with these written directives via pre- and post-treatment checks by the AMP and AU (for HDR and manual brachytherapy); capsule and vial assays (for I-131); and post-injection surveys and SPECT imaging (for microspheres).

The inspector also reviewed a selection of other records, including RSC meeting minutes, health physics consultant audits, documentation of blood irradiator preventative maintenance (including leak tests), documentation of HDR spot checks, source exchanges and full calibrations, various routine nuclear medicine records, and personnel dosimetry.

The licensee was previously cited in IR 03002009/2016001(DNMS) for a violation of security-related requirements. The inspector reviewed the licensee's corrective actions, which appeared to be adequate, and identified no additional examples of recurrence. This violation is therefore closed. No other violations of NRC requirements were identified as a result of this inspection.