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
Henry Ford Allegiance Health 205 N. East Avenue Jackson, MI 49201 REPORT NUMBER(S) 2020001	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
030-01990	21-00258-06	February 27, 2020; Exit March 19, 2020

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)

License Condition No. 13.A of NRC License No. 21-00258-06 states, in part, that the licensee shall conduct its program in in accordance with the statements, representations, and procedures contained in the Application dated February 4, 2011 (Application).

Section 8.25 of the Application, under section titled "Safe Use of Unsealed Licensed Material," states that the licensee has developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301 (Procedure).

(Continued on Part 2)

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	Samir Parikh MD, RSO		3-25-20
NRC INSPECTOR	Edward F. Harvey	Edward Harvey Digitally signed by Edward Harvey Date: 2020.03.19 15:36:24 -04'00'	3/19/2020
BRANCH CHIEF	Robert Ruiz	Christine A. Lipa Digitally signed by Christine A. Lipa Date: 2020.03.23 19:43:45 -05'00'	

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(Continued)

Item 7 of the licensee's Procedure titled "Tier 3: Nuclear Medicine Radiation Safety - Rules for Safe Use of Radiopharmaceuticals," states, in part, that staff wear personal monitoring devices (radiation badge) at all times while in areas where radioactive materials are used or stored.

Contrary to the above, on February 27, 2020, a member of the licensee's staff performed a diagnostic administration of radioactive material and did not wear their assigned personal monitoring device (radiation badge) during the administration.

The root cause of the violation was an oversight on behalf of the individual performing the administration. As corrective actions, the licensee (1) provided education for all designated nuclear medicine service providers regarding expectations surrounding radiation badge compliance, which was completed on March 3, 2020; (2) as of March 2, 2020, implemented a "time-out" process prior to the sentinel node injection process in which nuclear medicine technologists will check with all team members to ensure everyone is wearing their monitoring device prior to the administration; and (3) individually coached the staff member who performed that administration of radioactive material without a monitoring device on the importance of wearing their monitoring device during administrations.

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

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02120	3	Amy Helton, Imaging Manager	(517) 205-5164

☑ Main Office Inspection Next Inspection Date: February 27, 2023

☑ Field Office Inspection 309 Page Avenue, Jackson, MI 49201

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of a hospital authorized to possess and use unsealed byproduct material for diagnostic and therapeutic medical procedures at two locations in Jackson, Michigan. At the main hospital, the licensee staffed two nuclear medicine technologists (NMTs) who performed 10-15 diagnostic administrations per day and approximately three therapeutic administrations of iodine-131 per month. The location on Page Avenue was a cardiology center that staffed between one and two NMTs who performed approximately six diagnostic administrations for cardiac stress tests per day. No therapeutic administrations were performed at the Page Avenue location.

The inspector toured both facilities in Jackson to evaluate the licensee's measures for material security, hazard communication, and exposure control. The inspector observed administrations of licensed material for a sentinel node procedure, a cardiac stress test, and a therapeutic administration of I-131 for hyperthyroidism. The inspector observed the NMTs demonstrate package receipt procedures, dose calibrator quality control, and area survey procedures. The NMTs also demonstrated adequate knowledge of radiation protection principles and emergency procedures through interviews with the inspector.

The inspector reviewed a selection of licensee records, including quarterly audits, written directives, patient release calculations, patient release instructions, equipment calibrations, source inventories, survey meter calibration records, package receipt logs, and dosimetry with no issues noted. In addition, the inspector performed independent surveys at each location, which revealed no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

One violation of NRC requirements, described in Part 1 of this report, was identified during this inspection.