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
Major Hospital 2451 Intelliplex Dr. Shelbyville, IN 46176 REPORT NUMBER(S) 2019001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-08191	13-14877-01	May 1, 2019

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. IR-2016001

☐ 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 Sulaiman	5/1/19
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		5/17/19

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
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030-08191	13-14877-01	May 1, 2019

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02120	3	Ty A. Montgomery, M.D., RSO	(317) 421-5657

☑ Main Office Inspection Next Inspection Date: 05/01/2022

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, unannounced inspection of a community hospital with authorization to use byproduct materials under 10 CFR Sections 35.100, 35.200, and 35.300. The nuclear medicine department was staffed with two full-time and a part-time nuclear medicine technologists (NMTs). The NMTs typically administered approximately 140 diagnostic doses monthly, 3 radium-223 (Ra-223 Xofigo) and 2-3 iodine-131 (I-131 in capsule form) therapy doses annually. The diagnostic procedures using technetium-99m (Tc-99m) primarily for cardiac, gastric emptying, HIDA, and bone scan.

Performance Observations:

The inspection consisted of interviews with select licensee personnel, a review of selected records, and a tour of the nuclear medicine department. The inspector observed preparation and administration of Tc-99m for diagnostic procedures on a patient. The inspector: (1) observed the NMT conduct a physical inventory of sealed sources, and all sources were accounted for; (2) had the NMT demonstrate the package receipt surveys and wipes, dose calibrator constancy check, daily area surveys and weekly wipe tests, and proper handling of radioactive waste and disposal procedures. The inspector reviewed written directives for I-131 and Ra-223 therapies procedures. Interviews with licensee personnel indicated adequate knowledge of radiation safety, emergency procedures, and NRC regulations.

The inspector reviewed the following selected records: quarterly program audits, package receipts, waste disposal records, DOT Hazmat training, linearity and accuracy of the dose calibrator, instrument calibration, sealed source leak tests, daily area surveys, and weekly wipe tests. The inspector reviewed the dosimetry records for 2017 and through December 31, 2018 indicating the maximum annual dose to be 582 mrem - DDE; and 4,127 mrem - SDE. The inspector conducted independent and confirmatory surveys and found no residual contamination or exposures to members of the public in excess of regulatory limits.

The inspector reviewed and verified the licensee corrective action for a violation of 10 CFR 35.75(c). The licensee performed and implemented the patient release criteria calculation for all I-131 therapy patients. The inspector closed the violation

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