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
St. John Macomb-Oakland Hospital Macomb Center 11800 E. 12 Mile Road Warren, Michigan 48093 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
030-02005	21-01190-05	June 10-11 , 2015

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	Geoffrey M. Warren		6/11/15
BRANCH CHIEF	Aaron T. McCraw		6/22/15

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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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	Laura T. Smith, M.S., RSO	(586) 215-5947

☑ Main Office Inspection Next Inspection Date: June 2017

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced, inspection. The licensee was a 450-bed hospital located in Warren, Michigan, that used byproduct materials in Sections 35.100, 35.200, 35.300, and 35.400, as well as iridium-192 in an HDR unit under 35.600. Licensed activities were conducted only at the facilities identified on the license. According to the RSO, activities at the Madison Heights facility were limited to diagnostic nuclear medicine procedures. The licensee was considering adding yttrium-90 microspheres therapy and iodine-125 breast seed implantation to the license.

The nuclear medicine department at the main hospital was staffed with three full-time and one part-time nuclear medicine technologists. The nuclear medicine staff typically administered 350 diagnostic doses monthly, predominantly tecnhetium-99m cardiac, bone, and hepatobiliary studies. Doses were received as unit doses or prepared from bulk technetium received from a licensed radiopharmacy. The staff also performed around eight iodine-131 cancer and hyperthyroidism therapy procedures monthly, with the doses in capsule form.

The radiation therapy department was staffed with two physician authorized users and one medical physicist; additional physicists were available when needed. The radiation therapy staff treated approximately two HDR patients monthly; treatments ranged from three to ten fractions per patient. HDR procedures included prostate, breast, gynecological, endobronchial, and occasional interstitial treatments. In addition, the therapy staff performed around three to four prostate implant procedures annually, using iodine-125 seeds only.

Performance Observations: The inspector observed one HDR fraction and one diagnostic administration of licensed material, including dose preparation and disposal; as well as package receipt surveys and wipes. Licensee staff demonstrated or described daily checks in nuclear medicine, daily checks of the HDR unit, HDR planning, permanent prostate implants, diagnostic and therapeutic nuclear medicine procedures, kit preparation, and daily and weekly contamination surveys. The inspector reviewed written directives for all therapy modalities and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of regulatory concern. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. Radiation Safety Committee meeting minutes indicated good attendance and discussion of appropriate topics.