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, MI 48093 REPORT NUMBER(S) 2013-001	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	March 18-19, 2013

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	Deborah A. Piskura, Health Physicist	Deborah A. Piskura	3/19/2013
BRANCH CHIEF	Tamara E. Bloomer, Chief, MIB	Tamara E. Bloomer	3/27/13

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
87130, 87131, 87132	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: March 2015

☑ Field Office Inspection 27351 Dequindre Ave. Madison Hts, MI

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This licensee was a medical institution (260+ bed hospital) and conducted licensed activities at two locations in the suburban Detroit area. This licensee's authorization included materials in Sections 35.100, 35.200, 35.300, 35.400, 35.500, and Ir-192 in in an HDR unit. The daily radiation safety activities were managed by a full time RSO. The licensee's consulting physicist audited the radiation safety program on a quarterly basis. Collectively, the nuclear medicine departments performed approximately 300+ diagnostic nuclear medicine procedures monthly which included a full spectrum of diagnostic imaging studies. The department maintained an active therapy program and administered numerous I-131 dosages (capsules only) for CA, whole body follow up studies, and hyperthyroidism. No beta radiopharmacueticals were administered by this licensee.

The radiation therapy activities under this license were performed at the main hospital in Warren. The radiation oncology department was staffed with 4 AMPs, 2 dosimetrists, and 6 authorized users. The licensee administered 20-30 I-125 permanent prostate implants each year. The majority of the department's activities involved the HDR unit which the licensee administered approximately 150 patient treatments per year; the majority of these treatments were for breast, bronchial/lung, prostate and gynecological cancers. All HDR patient treatments were administered by the attending radiation oncologist and the authorized medical physicist. Service, maintenance, and source exchanges were performed by the HDR device manufacturer.

This inspection consisted of interviews with select licensee personnel; a review of select records; tours of the nuclear medicine and radiation oncology departments; and independent measurements. The inspector observed the administration of several diagnostic nuclear medicine procedures. The inspector also observed the licensee staff administer a patient treatment utilizing its HDR unit at the main hospital. The inspection included observations of dose calibrator QA checks, HDR QA and safety checks, security of byproduct material, use of personnel monitoring, package receipts, and patient surveys. The inspector determined that the licensee had implemented corrective actions as described in the inspection report 030-02005/2012-001(DNMS) and the enforcement action (EA-12-172). The licensee revised its policies and procedures to incorporate a "time out" process in their procedures to verify the HDR treatment set up. The licensee provided training to its staff on its revised policies and procedures.