

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Henry Ford Macomb Hospital
15855 Nineteen Mile Road
Clinton Township, MI 48038

REPORT NUMBER(S) 2012-001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-02106

4. LICENSE NUMBER(S)

21-11850-01

5. DATE(S) OF INSPECTION

Feb 15, 2012

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 violation(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	<i>DAPiskura</i>	2/15/2012
BRANCH CHIEF	Tamara E. Bloomer	<i>Tamara Bloomer</i>	2/23/12

Docket File Information

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3. DOCKET NUMBER(S) 030-02106	4. LICENSE NUMBER(S) 21-11850-01	5. DATE(S) OF INSPECTION Feb. 15, 2012	
6. INSPECTION PROCEDURES USED 87130, 87131, 87132	7. INSPECTION FOCUS AREAS 03.01-07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Khurram Rashid, M.D., RSO	4. TELEPHONE NUMBER (586) 263-2400
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☒ Main Office Inspection Next Inspection Date: Feb. 2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This licensee was a large medical institution (300+ bed hospital) and authorized to use materials in Sections 35.100, 35.200, 35.300, 35.400, 35.500, Ir-192 in an HDR unit. The licensee's consulting physicist audited the radiation safety program on a quarterly basis.

The nuclear medicine department performed approximately 500 diagnostic nuclear medicine procedures monthly which included a full spectrum of diagnostic imaging studies. The licensee received unit doses and bulk Tc-99m. The department maintained an active therapy program and administered numerous I-131 dosages for CA, whole body follow up studies, and hyperthyroidism. Occasionally, the department administered I-131 Bexxar, and Y-90 Zevalin dosages; no cases since the last routine inspection.

The radiation oncology department was staffed with 3 AMPs, 2 dosimetrists, and 3 authorized users. The majority of the department's activities involved the HDR unit. The licensee administered 5-10 I-125 permanent prostate implants each year. The licensee utilized its HDR unit to administer approximately 30-40 patient treatments per year; the majority of these treatments were for breast, bronchial/lung, and gynecological cancers. All HDR patient treatments were administered by the attending radiation oncologist, the AMP, and a therapy technologist. Service, maintenance, and source exchanges were performed by the 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. The inspector reviewed the patient's written directive and the treatment plan and interviewed the attending physician and AMP. 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.