NRC FORM 591M PART 1
(1-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

# SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| 1. LICENSEE/LOCATION INSPECTED: | 2. NRC/REGIONAL OFFICE |
|---|---|
| Mount Clemens Regional Medical Center<br>1000 Harrington Blvd.<br>Mount Clemens, MI 48326<br><br>REPORT NUMBER(S) 2012-001 | Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-02040 | 21-04080-01 | Feb 16, 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 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 | Deborah A Piskura | 2/16/2012 |
| BRANCH CHIEF | Tamara E. Bloomer | Tamara Bloomer | 2/23/12 |

NRC FORM 591M PART 3
(1-2012)
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 |
|---|---|
| Mount Clemens Regional Medical Center<br>1000 Harrington Blvd.<br>Mount Clemens, MI 48326<br><br>REPORT NUMBER(S) 2012-001 | Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-02040 | 21-04080-01 | Feb. 16, 2012 |

| 6. INSPECTION PROCEDURES USED | 7. INSPECTION FOCUS AREAS |
|---|---|
| 87130, 87131, 87132 | 03.01-07 |

## SUPPLEMENTAL INSPECTION INFORMATION

| 1. PROGRAM CODE(S) | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| 02230 | 2 | Arthur J. Frazier, M.D., RSO | (313) 466-8090 |

☑ Main Office Inspection  Next Inspection Date: Feb 2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection

## PROGRAM SCOPE

This licensee was a medical institution (280+ bed hospital) and authorized to use materials in Sections 35.100, 35.200, 35.300, 35.400, Ir-192 in an HDR unit. The licensee's consulting physicist audited the radiation safety program on a quarterly basis (last 11/2/2011, with no findings).

The nuclear medicine department was staffed with 7 technologists who performed approximately 400 diagnostic nuclear medicine procedures monthly. These studies included a full spectrum of diagnostic imaging procedures. 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; 1-2 cases annually.

The radiation oncology department was staffed with 2 AMPs and 2 authorized users. The licensee administered 50 I-125 permanent prostate implants each year. The licensee utilized its HDR unit to administer approximately 50 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 and the AMP. 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 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.