NRC FORM 591M PART 1
(06-2010)
10 CFR 2.201

U.S NUCLEAR REGULATORY COMMISSION

# SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| 1. LICENSEE/LOCATION INSPECTED: | 2. NRC/REGIONAL OFFICE |
|---|---|
| Henry Ford Macomb Hospital – Warren Campus<br>13355 East Ten Mile Road<br>Warren, Michigan 48089<br>REPORT NUMBER(S): 2011-001 | U.S. Nuclear Regulatory Commission, Region III<br>2443 Warrenville Road, Suite 210<br>Lisle, Illinois 60532 |

| 3. DOCKET NUMBER(S) | 4. LICENSEE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-02042 | 21-04082-01 | February 23, 2011 |

**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:

[X] 1. Based on the inspection findings, no violations were identified.

[X] 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, NUREG-1600, 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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

**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 | GJ W | 2/28/11 |
| Branch Chief | Tamara E. Bloomer | Robert D. Hatten, Jr. for | 2/28/11 |

NRC FORM 591 M PART 3 (06-2010) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

*Docket File Information*

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| 6. INSPECTION PROCEDURES | 7. INSPECTION FOCUS AREAS |
|---|---|
| 87131, 87132 | 03.01 – 03.08; 03.01 – 03.08 |

**SUPPLEMENTAL INSPECTION INFORMATION**

| 1.PROGRAM | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| 02120 | 3 | Donald J. Peck, Ph.D., RSO | 313-916-7335 |

☒ Main Office Inspection — Next Inspection Date: Feb. 2014

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

**PROGRAM SCOPE**

The licensee was a 212-bed medical facility located in Warren, Michigan, with authorization to use byproduct materials in Sections 35.100, 35.200, 35.300, and 35.400. Licensed activities were conducted only at the facility identified on the license.

The nuclear medicine department was staffed with two full-time nuclear medicine technologists. The licensee's nuclear medicine staff typically administered 130 diagnostic doses monthly and 25 iodine-131 therapy doses annually, with the iodine in capsule form; iodine therapies had decreased significantly since the previous inspection. The diagnostic procedures were predominately technetium-99m cardiac, bone, and hepatobiliary imaging, as well as iodine-125 thyroid scans. The department received daily unit doses from a licensed nuclear pharmacy. All waste was either held for decay-in-storage (DIS) or returned to the radiopharmacy.

The radiation therapy procedures were performed primarily by personnel from other facilities, though the procedures were performed at the hospital. Patient charts, including post-plans, were filed at the referring facilities, primarily MIRO facilities, though documentation of seed ordering and receipt, pre-plans, and seed implantations were maintained in the nuclear medicine department. The radiation therapy staff performed approximately one to two permanent prostate implant procedures monthly using iodine-125 seeds.

**Performance Observations**

The inspector observed three diagnostic administrations of licensed material, including dose preparation and disposal, as well as a package receipt survey. Licensee personnel demonstrated dose calibrator constancy, well counter and survey meter QC, and daily and weekly contamination surveys, and described additional diagnostic and therapeutic administrations. The inspector noted no issues with these activities. The inspector reviewed written directives for radiopharmaceutical and prostate implant procedures. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The inspector closed a violation from the previous inspection concerning the performance of iodine-131 therapeutic treatments without the Authorized User first signing the written directive. A review of written directives for iodine-131 therapies indicated that all had been signed prior to administration.