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 |
|---|---|
| Oakwood Hospital-Annapolis Center<br>Wayne, MI<br>REPORT NUMBER(S) 2011-001 | U.S. Nuclear Regulatory Commission<br>Region III<br>2443 Warrenville Road<br>Lisle, IL 60532 |

| 3. DOCKET NUMBER(S) | 4. LICENSEE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-02099 | 21-11457-02 | August 8, 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:

☒ 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, 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 | Deborah A. Piskura | Deborah A. Piskura | 8/8/2011 |
| Branch Chief | Tamara E. Bloomer | Tamara E. Bloomer | 8/22/11 |

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

U.S. NUCLEAR REGULATORY COMMISSION

*Docket File Information*

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

| 1. LICENSEE | 2. NRC/REGIONAL OFFICE |
|---|---|
| Oakwood Hospital – Annapolis Center<br>33155 Annapolis Avenue<br>Wayne, MI 48184<br>REPORT NUMBER(S) 2011-001 | U.S. Nuclear Regulatory Commission<br>Region III<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4351 |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-02099 | 21-11457-02 | August 8, 2011 |

| 6. INSPECTION PROCEDURES | 7. INSPECTION FOCUS AREAS |
|---|---|
| 87130 | 03.01-03.08 |

**SUPPLEMENTAL INSPECTION INFORMATION**

| 1.PROGRAM | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| 2120 | 3 | Ashok Jain, M.D., RSO | 734-467-4143 |

⊘ Main Office Inspection — Next Inspection Date: unchanged____

Field Office Inspection

☐ Temporary Job Site Inspection _____

**PROGRAM SCOPE**

This was special follow up inspection to review the licensee's corrective actions in response to escalated enforcement action involving a medical event. Specifically, on December 4, 2010, a nuclear medicine technologist mistakenly gave a patient approximately 124.5 millicuries of bulk Tc-99m rather than the intended dosage of 10 millicuries of Tc-99m Myoview™ for a resting cardiac study. As a result, the patient received a dose to the upper lower intestine of approximately 27 rads and a whole body equivalent dose of approximately 6 rem which exceeded the prescribed dosage by more than 20 percent. Two violations of NRC requirements were identified: (1) 10 CFR 35.63(d), using a dosage that differed from the prescribed dosage by more than 20 percent without being directed by an authorized user, and (2) Condition 15 of NRC License No. 21-11457-02, failure to verify the quantity of byproduct material and the physical/chemical form of the dosage prior to the administration.

This inspection verified the licensee's corrective actions which included: (1) increasing the supervision of the technologist directly involved with the medical event; (2) instructing the nuclear medicine staff on the hospital's policies and procedures for handling doses prior to administration which included documentation of competency training; (3) implementing random staff audits to evaluate performance including assays of doses prior of administration; (4) requesting that the nuclear pharmacy dispense the hospital's standing orders of bulk Tc-99m in vials only; and (5) changing the hot lab configuration to physically separate and color-code the bulk quantity to Tc-99m (from other unit doses). The inspector observed licensee staff prepare, assay and administer several dosages for various diagnostic imaging studies. No violations were identified during this follow up inspection and the previous violations were considered closed.