INSPECTION RECORD

Region: III **Inspection Report No.** 2016001 **License No.** 21-11457-02
Docket No. 030-02099

Licensee: Oakwood Hospital – Annapolis Center
33155 Annapolis Avenue
Wayne, MI 48184

Locations Inspected: Same as above

Licensee Contact: Ashok Jain, MD, RSO **Telephone No**. (734) 467-4143

Program Code: 02121 **Priority**: 5

Type of Inspection: ( ) Initial (X) Routine ( ) Announced
( ) Special (X) Unannounced

Last Inspection Date: August 8, 2011 **Date of This Inspection**: 04/08/2016

Next Inspection Date: 04/08/2021 (X) Normal ( ) Reduced

Summary of Findings and Actions:

(X) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector Edward Harvey, Health Physicist

/RA/ Date 5/3/2016
Signature

Approved Aaron McCraw, Chief, MIB

/RA/ Date 5/6/2016
Signature

PART I – LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
38	10/01/2015	Added authorized user for 10 CFR 35.100 and 35.200 procedures
37	10/20/2014	Change of ownership
36	03/24/2014	Change of location of stress lab
35	05/28/2013	Removal of 10 CFR 35.400 authorization from license
34	04/22/2011	Change in Radiation Safety Officer (RSO)

The active NRC license expires on May 31, 2021.

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection of this licensee was an enforcement follow-up on August 8, 2011. No violations of NRC requirements were identified.

The last routine inspection of this licensee was on December 14, 2010. During this inspection, the inspector identified violations of 10 CFR 35.63(d) and License Condition No. 15. A. Specifically, the licensee failed to have appropriate procedures in place to verify that the administered dose was within 10 percent of the prescribed dose, which resulted in an overdose to a patient. These violations were categorized as a Severity Level III problem.

3. INCIDENT/EVENT HISTORY:

NMED Item 110107 involved six prostate seed implant overdoses that exceeded 120 percent of the prescribed dose, which could have potentially been classified as reportable medical events. In accordance with the NRC's Interim Enforcement Policy (IEP) regarding "Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)" (RIS 2013-10), enforcement discretion was warranted for failure to report these overdoses as medical events to the NRC. As a result, NMED Item 110107 was considered closed.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Oakwood Hospital – Annapolis Center (licensee) is a 215-bed hospital authorized under NRC Materials License No. 21-11457-02 to use byproduct material permitted by 10 CFR 35.100 and 35.200. The nuclear medicine department, which operated seven

days per week, staffed two full-time and two part-time nuclear medicine technologists (NMTs). Approximately 8-10 administrations were performed per day, all using unit doses of technetium-99m (Tc-99m) for the full spectrum of studies.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130

Focus Areas Evaluated: All

The inspector observed nuclear medicine staff demonstrate package receipt and surveying procedures, daily dose calibrator constancy checks, daily surveys, and waste disposal procedures. The inspector also observed a chemically induced stress test injection and noted that the technologist was wearing the appropriate personal protective equipment, properly assayed the dose, and maintained ALARA practice throughout the entire administration procedure.

The technologists demonstrated adequate knowledge of emergency procedures in the event of a spill or contaminated package through interview with the inspector. All material was adequately labeled and secured in the hot lab, which remained closed and locked when not under the surveillance of authorized personnel.

The inspector reviewed a selection of licensee records, including program audits, dose calibrator linearity records, dose calibrator accuracy records, source inventories, survey meter calibration records, package receipt logs, and dosimetry records. The highest reported dose reviewed was 280 millirem (mrem) DDE and 272 mrem SDE.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector conducted independent surveys at various locations within the hot lab and the nuclear medicine department. The inspector found no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

No violations were identified during this inspection.

5. PERSONNEL CONTACTED:

Ashok B. Jain, MD, Chief of Staff
Piyush Pandya, Chief NMT
Sandy Taylor, Administrator

Attended exit meeting on April 8, 2016.