INSPECTION RECORD

Region: III **Inspection Report No.** 2015001 **License No.** 21-32250-01
Docket No. 030-35444

Licensee: Scheurer Hospital
170 North Caseville Road
Pigeon, MI 48755

Locations Inspected: 170 North Caseville Road, Pigeon, MI

Licensee Contact: David Dubriwny, DO - RSO **Telephone No**. 989-453-3223

Program Code: 02121 **Priority**: 5

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

Last Inspection Date: 06/26/2012 **Date of This Inspection**: 10/22/2015

Next Inspection Date: 10/22/2020 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval: N/A

Summary of Findings and Actions:

( ) 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
(X) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspectors: Luis Nieves, Health Physicist

/RA/ Date ***11/10/2015***
Signature

Ryan Craffey, Health Physicist

/RA/ Date ***11/10/2015***
Signature

Approved: Aaron McCraw, Chief, MIB

/RA/ Date: ***11/10/2015***
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
08	09/30/15	Changed RSO, provided notification of nuclear medicine department relocation
07	02/09/15	Changed RSO, removed 35.300 authorization

2. INSPECTION AND ENFORCEMENT HISTORY:

The NRC last conducted a routine inspection of Scheurer Hospital on June 26, 2012. No violations of NRC requirements were identified as a result of this inspection.

Prior to that, the NRC conducted a routine inspection of this licensee on May 12, 2009. No violations of NRC requirements were identified as a result of that inspection, either.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Scheurer Hospital was authorized by NRC Materials License 21-32250-01 to use radioactive material for diagnostic administrations of radiopharmaceuticals at its facility in Pigeon, Michigan. At the time of the inspection, one full-time and one part-time nuclear medicine technologist performed around five administrations per day, primarily in the mornings between 6 am and 12 pm, using unit doses from a nearby licensed radiopharmacy. The licensee retained the services of a medical physics consultant to review the content and implementation of its radiation safety program quarterly.

On November 3, 2014, the licensee requested removal of authorization for therapeutic administrations of radiopharmaceuticals from its license, as it had not performed any such procedures since before the last inspection. On February 9, 2015, the NRC issued a license amendment to reflect that request. The licensee also recently began construction of a new nuclear medicine department at its existing facility in Pigeon. On September 14, 2015, the licensee notified the NRC of its intent to relocate the department, estimated at the time of the inspection to occur within the next year.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130

Focus Areas Evaluated: All

The inspectors toured the facility in Pigeon to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspectors were unable to observe the administration of any radiopharmaceuticals, as the licensee had completed all scheduled administrations before the inspectors arrived. Instead, the licensee's staff demonstrated the implementation of licensee procedures for dose preparation and administration, as well as procedures for receipt of packages containing radioactive material and waste handling. The inspectors also observed the licensee's staff conduct surveys of the facilities, and discussed spill response with the staff.

The inspectors also reviewed a selection of relevant records, including dose calibrator quality control documentation, quarterly consultant audits, training records including hazmat, and dosimetry.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-9 pancake probe calibrated on January 5, 2015, the inspectors conducted independent surveys in and around the licensee's nuclear medicine department. The inspectors found evidence of residual contamination or exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

On October 22, 2015, the inspectors identified a violation of Condition 14.A of NRC Materials License 21-32250-01 for the licensee's failure to conduct its radiation safety program in accordance with the "Rules for Safe Use of Radiopharmaceuticals" procedure established in the license renewal application dated May 17, 2010. The inspectors found that the licensee's respiratory therapists had administered two cardiac stress tests that day using unit doses of technetium-99m, and had not worn extremity monitoring devices while performing these administrations, as required by Item 4 of the abovementioned procedure.

The licensee indicated that the therapists routinely assisted the nuclear medicine technologists in performing cardiac stress tests, up to and including administering the dose provided by the technologists, as had been done today. The respiratory therapists had received training in radiation safety topics annually, but had not been given extremity monitoring devices.

The inspectors determined that the root cause of the violation was less than adequate management oversight, in that the licensee was unaware that the therapists were also required to wear extremity monitoring according to the established procedure.

As corrective action to restore compliance and to address the potential for recurrence, the staff committed to obtain extremity monitoring for the nurses, and to limit the handling of radioactive material to those who already have extremity monitoring in the meantime. In addition, the staff committed to review the procedure for safe use of radioactive material with your medical physics consultant.

5. PERSONNEL CONTACTED:

Laurie Polega, Diagnostic Imaging Service Leader
Joe Siemen, Nuclear Medicine Technologist

Attended exit meeting on October 22, 2015