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
Oaklawn Hospital 200 N. Madison Marshall, Michigan REPORT NUMBER(S): 11-01	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-12139	21-17038-01	November 16, 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

One Severity Level IV violation was identified by the NRC and is described in the attached Part 2.

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	Sharon L. Thomas-Bayle	Sharon Thomas-Bayle	11/16/11
NRC INSPECTOR	Andrew M. Bramnik	Andrew M Bramnik	11/16/2011
Branch Chief	Tamara E. Bloomer	for TEB	11/23/11

NRC FORM 591M PART 2
(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
Oaklawn Hospital REPORT NUMBER(S) 11-01	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-12139	21-17038-01	November 16, 2011

(Continued)

Condition 15 of NRC License No. 21-17038-01 requires the licensee, in part, to ~~comply with the~~ conduct its program in accordance with the statements, representations, and procedures contained in the Application dated September 3, 2003.

Item 10 (8.24) of the Application dated September 3, 2003, states, in part, that the licensee has "developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."

The licensee's procedure titled "Rules for Safe Use of Radiopharmaceuticals" states in Item 1 "wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used;" and states in Item 2 "wear disposable gloves at all times while handling radioactive materials."

Contrary to the above, on November 16, 2011, the licensee handled and used unsealed byproduct material and did not adhere to the procedure titled "Rules for safe use of Radiopharmaceuticals." Specifically, a licensee technologist ~~handled~~ injected a patient with unsealed byproduct material and was not wearing either a laboratory coat or gloves.

The root cause of the violation was an accidental oversight by the technologist, [redacted] As corrective actions, the licensee's staff will always wear laboratory coats and gloves, keep extra lab coats available, and store extra gloves in injection areas. These actions were completed on November 16, 2011.

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

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3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-12139	21-17038-01	November 16, 2011

6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
87130	03.01 – 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1.PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2121	5	Anthony Horabin, RT(N) – Asst. Radiology Dir.	269-789-3917 x.3348

☒ Main Office Inspection — Next Inspection Date: November 2016

☐ Field Office Inspection

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a 77 bed hospital that performed approximately 30 diagnostic nuclear medicine procedures per week. Two full time nuclear medicine technologists performed all patient procedures. The licensee obtained unit doses and occasional bulk doses of licensed material from an area nuclear pharmacy, and did not use xenon-133 or molybdenum/technetium generators. The licensee performed primarily cardiac, bone, gall bladder, and gastric empyting scans. The licensee was not authorized to administer therapeutic doses of licensed material.

PERFORMANCE OBSERVATIONS

The inspector observed two stress doses of technicium-99m being administered during the inspection. A technologist administered one dose without wearing a laboratory coat or gloves, contrary to the licensee's procedures. This item is described in Parts 1 and 2 of this report. The licensee successfully described or demonstrated dose calibrator constancy checks, package receipt, daily surveys, and waste handling and disposal procedures. An outside consultant performed quarterly program audits that were adequate to oversee the program.

Licensed material was adequately secured and not readily accessible to members of the general public. The licensee possessed a radiation survey meter that was calibrated, operational, and performed well in side-by-side comparison with an NRC instrument. Independent measurements did not indicate readings in excess of Title 10 of the Code of Federal Regulations (10 CFR) Part 20 limits in restricted or unrestricted areas. Personal whole body and extremity dosimetry were observed being worn by the staff during the inspection, and records did not indicate doses in excess of 10 CFR Part 20 limits. Dosimetry records indicated that the highest annual whole body and extremity readings for the past four years were 141 millirem (mrem) and 40 mrem, respectively.

One Severity Level IV violation was identified during this inspection, and is described in Parts 1 and 2.