NRC FORM 591 PART 1
(8-1997)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY AND COMPLIANCE INSPECTION

1. LICENSEE	2. REGIONAL OFFICE
OAKLAWN HOSPITAL 200 N. MADISON MARSHALL, MI 49068 REPORT NUMBER(S)	REGION III US NUCLEAR REGULATORY COMMISSION 801 WARRENVILLE ROAD LISLE IL 60532-4351

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-12139	21-17068-01	9/15/00

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. 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): _____

☐ 3. 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 is required to be posted 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			
NRC INSPECTOR	TONY GO	[signature]	9/15/00

NRC FORM 591 PART 1 (8-1997)

INSPECTOR

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Region **III**

Inspection record No. **2000-001** License No. **21-17068-01**

Licensee (Name and Address): Docket No. **030-12139**

Oaklawn Hospital
200 North Madison
Marshall, MI 49068

Location (Authorized Site) Being Inspected:
200 N. Madison
Marshall, MI

Licensee Contact: **Robert Zick, MD** Telephone No. **(616) 781-4271**
Priority: **5G** Program Code: **2120**

Date of Last Inspection: **06/29/95** NMED/Event No(s).: **None**
Date of This Inspection: **09/15/00**

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

Next Inspection Date **9/2007** ( ) Normal ( ) Reduced (**X**) Extended

Justification for change in normal inspection frequency:
In accordance with MC 2800, Materials Inspection Branch is extending this licensee's inspection frequency for good performance based on the last two inspections.

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
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Followup on previous violations

Inspector(s) ***/RA/*** Date 9/18/00
Tony S. Go

Approved ***/RA/*** Date 9/21/00
Geoffrey Wright, Chief of M.I.B.

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

1. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations including NCVs; Confirmatory Action Letters; and orders)
The licensee was given a "Clear" inspection on the last inspection dated 06/29/95. There were no violations identified on this inspection.

2. INCIDENT/EVENT HISTORY:
(List any incidents, recordable events, or misadministrations reported to NRC since the last inspection. Citing "None" indicates that the NRC nuclear material events database, regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

An interview with the licensee's technologist and a review of the licensee's incident records indicated that, the licensee had not experienced events such as dose misadministrations. The licensee does not administered I-131 therapy doses. In addition, the licensee has not experienced any accidents associated with the used of byproduct materials such as a large spill. No violations were found during the inspection.

PART II - INSPECTION DOCUMENTATION

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that all focus elements are to be addressed during each inspection.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organization; authorities and responsibilities; authorized locations of use; type, quantity, and frequency of byproduct material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; and research involving human subjects)

The licensee is a small nuclear medicine department performing approximately 45 nuclear medicine studies per month. The licensee is a 95-bed hospital servicing Marshall, Michigan. The licensee orders unit doses from Syncor pharmacy and on occasion the licensee orders unit doses from Spectrum pharmacy. The

licensee does not possess Mo99/Tc-99m generators nor conducts ventilation lung scans with Xe-133. The licensee had submitted a QMP program in 1994; however, they have not implemented the program since the last inspection. The license is limited to 10 CFR 35.100 and 200 programs "only." The licensee employs two N.M. Technologists. The license authorizes seven physicians under License Condition No. 12. As of the inspection date, the licensee administered iodine-123 uptakes and scans, and the licensee had not performed Xe-133 studies since the last inspection. On a typical day, the licensee's procedures are consisted of 60 percent of cardiac stress studies, and 40 percent of other diagnostic procedures. The cardiac studies are strictly performed with Tc-99m Cardiolite doses ordered from Syncor pharmacy. The licensee did not perform human research studies with NRC licensed materials since the last inspection. The licensee retains MPC, James Botti, a consultant to perform quarterly audits for the past eight years.

2. PERSONNEL CONTACTED:
(Identify licensee personnel contacted during the inspection [including those individuals contacted by telephone].)
Robert Covert, Administrator
Robert Zick, MD, RSO
Richard Johnson, Director of Radiology
Ron Walton, CNMT
Kimberly Hubbart, CNMT

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)
Ludlum 2403 NRC#072517 Calibration Date: 12/16/99
The inspector performed radiation surveys in the new nuclear medicine room that was approved on 03/96 amendment. The radiation surveys at restricted and unrestricted areas including the hot lab inside the nuclear medicine room indicated radiation levels near background of <.03 mR/hr (7nC/kg/hr). The highest readings were found within 30 cm from the waste storage in the hot lab and near the syringes behind a bio-shield in the hot lab. The highest reading at contact with waste containers and the unused unit doses was about 0.5 mr/hr (129 nC/kg/hr). The unrestricted areas at the nuclear medicine department's hallways did not indicate readings greater than background radiation of 0.03 mR/hr (7 nC/kg/hr).

The above survey results demonstrate that contamination was not identified at the licensee's facility, and radiation levels at the facility were at or below the NRC's limit for unrestricted areas.

No violations of NRC requirements were identified.

4. OTHER:

(e.g., posting and labeling)

The inspector noted the appropriate postings at the facility. These postings included NRC Form-3, "CAUTION: RADIOACTIVE MATERIAL" and "CAUTION RADIATION AREA" signs at the entrance to restricted area. Syringe containers containing unit doses were found labeled.

No violations of NRC requirements were identified.

PART III - FOCUS ELEMENTS

1. ADEQUATE PROGRAM SURVEILLANCE AND CORRECTIVE ACTIONS
YES _**X**__ NO___

(Adequate program reviews, including corrective actions for licensee findings and NRC- identified violations; resources [financial and personnel] dedicated to the program; recurring problems; radiation safety officer [RSO] present; RSO authority and effectiveness; radiation safety committee involvement [if required]; management support of program; radioactive material surveys)

Desired outcome: Problems associated with maintenance of equipment and radiation safety processes occur infrequently; when they do, they are properly identified and characterized, and effective corrective actions are implemented.

The licensee's radiation safety program is reviewed independently every quarter by MPC (James Botti), the licensee's consultant. Program reviews were found to be comprehensive. The results of reviews were presented quarterly to the Radiation Safety Committee (RSC). The inspector determined through interviews that the licensee's safety equipments such as survey instruments and a dose-calibrator is checked daily. A selective review of licensee audit records, survey records, and interviews of the staff technologist demonstrated that the licensee's personnel are aware of the status of materials receipt, control, transfer, storage, use, and disposal of licensed material. The records of RSC minutes indicated that the membership of the RSC met the specification of 10 CFR 35.22 (a) (1), and the RSC meetings held quarterly. No problems were identified with the RSC quorums.

Survey records from 01/13/99 through 08/10/00 showed that the licensee completed daily radiation level surveys for the restricted areas. These surveys indicated that there were no major contaminations. An interview with NM staff indicated that this individual was aware on the licensee's spill procedures. Records did not confirm a major spill since the last inspection.

Within the areas inspected, no concerns for management oversight or violations of NRC requirements were identified and the desired outcome was met.

2. KNOWLEDGEABLE STAFF AND MANAGEMENT YES **_X_** NO___

(Use by qualified and knowledgeable individuals; safe work practices; all levels of management possess sufficient knowledge to provide effective oversight of the program)
Desired Outcome: Information-based errors, associated with equipment usage and radiation safety processes, do not occur.

The licensee trains the nuclear medicine staff least annually in ALARA. The annual training involves written tests administered by the MPC consultant. The annual training is conducted by the RSO or by the the MPC consultant annually on emerging regulatory and safety issues. No problems were identified during the inspection.

3. OCCUPATIONAL AND PUBLIC DOSES WITHIN REGULATORY LIMITS
YES **_X_** NO___

(Offsite contamination events; effective event response; trending as low as reasonably achievable; release pursuant to 10 CFR 35.75; substantial potential for overexposure; monitoring and dose assessment program; release for unrestricted use; notification)

The inspector determined through interviews that the licensee has not had fires, explosions, lost/stolen radioactive material, over exposures, misadministrations/recordable events, nor package contaminations exceeding DOT limits from vendors. The licensee's radiation protection program involves external dose monitoring that includes both whole body and extremity dosimeters provided by R. S. Landauer. Dosimeters are exchanged on a monthly basis. A review of dosimetry reports from January 1998 to present indicated the following:

2000 TEDE = 161 mrem SDE = 1830 mrem
1999 TEDE = 223 mrem SDE = 1080 mrem
1998 TEDE = 200 mrem SDE = 1410 mrem

The licensee's dosimetry program are properly evaluated by the licensee's consultants and approved by the RSO. The RSO presented dose evaluations during the RSC quarterly meetings. Currently the program assures that occupational and public doses are kept below the applicable regulatory limits and are ALARA.

4. ADEQUATE SECURITY AND CONTROL OF LICENSED MATERIAL
YES **_X__** NO___

(Security and control measures commensurate with the hazard of the material involved; inventory; proper ordering, receipt and transfer of RAM; RAM in unrestricted/uncontrolled area; proper shipping; loss of RAM; proper disposal; notification)

The desired out come: No losses or unauthorized releases of licensed material with potential to deliver or result in overexposure.
The inspector verified through an interview that NRC-licensed materials have not been stolen or lost at the facility since the last inspection. All RAM materials (unit doses) are transported directly to the hot lab by the Syncor driver daily. The unit doses are delivered in Type-A packaging directly to the hot-lab each morning by the Syncor driver, and the hot lab secured after RAM delivery. To date, no licensed materials were released nor removed from the restricted area. The inspector did not identify problems with the licensee's radioactive material (RAM) inventory, security, ordering, receipt, use, transfer, and proper shipping and disposal of RAM.

Within the areas inspected, no violations of NRC requirements were identified and the desired outcome was met.

5 USE OF LICENSED MATERIAL ONLY AS AUTHORIZED YES _**X**__ NO___

(Authorized users, uses, types and quantities of materials, and locations; adequate supervision by authorized users)

The desired outcome: No unauthorized activities with licensed material having significant and credible potential for affecting safety.

The inspector verified that licensed materials are used by or under the supervision of RSO, Dr. Zick or by authorized individuals listed in the license. The licensee demonstrated that types and quantities of materials used, locations of use, and modalities are in accordance with the regulatory requirements and license conditions. Controls are being implemented by the licensee through the RSO, and in addition, the program is audited by MPC to ensure proper use of licensed materials.
Within the areas inspected, no violations of NRC requirements were identified and the desired outcome was met.

6. RADIOPHARMACEUTICAL ADMINISTRATIONS CONFORMING TO THE PHYSICIAN'S WRITTEN DIRECTIVES YES _**X**__ NO___

(Quality management program - written directives, implementation, reviews; Misadministrations - identification, notifications, reports, and records)

Desired outcome: Maintenance of an effective Quality Assurance (sic) program, to avoid misadministrations.

The inspector determined through interviews and record reviews that there were no misadministrations or radiopharmacy dispensing errors occurred since the last inspection. The staff involved in dose prescription, preparation, and administration have a clear understanding that doses are to be administered to patients as directed by authorized users. The inspector verified that the licensee

had not administered iodine-131 greater than 33 uCi {1.2 MBq} since the last inspection. The inspector also verified through record reviews that the licensee's had not implemented the quality management program to date.

Within the areas inspected, no violations of NRC requirements were identified and the desired outcome was met.

PART IV - POST- INSPECTION ACTIVITIES

1. DEBRIEF WITH REGIONAL STAFF:
(Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer, and/or State Liaison Officer)

A debriefing with the Branch Chief concerning this inspection was conducted on 09/18/2000.

2. OTHER:

NONE