

SAFETY AND COMPLIANCE INSPECTION

1. LICENSEE HAYES GREEN BEACH Mem. 321 E. HARRIS Street Charlotte, ME 08813 REPORT NUMBER(S)		2. REGIONAL OFFICE REGION III US NUCLEAR REGULATORY COMMISSION 801 WARRENVILLE ROAD LISLE IL 60532-4351	
3. DOCKET NUMBER(S) 030-31124		4. LICENSE NUMBER(S) 21-26050-01	
		5. DATE(S) OF INSPECTION 9/14/00	


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		9/11/00

APPENDIXA

NUCLEAR MEDICINE INSPECTION RECORD
(TEMPORARY INSTRUCTION 2800/029)

Region III

Inspection record No. 2000-001

License No. 21-26050-01

Licensee (Name and Address):

Docket No. 030-31129

Hayes Green Beach Memorial Hospital
321 East Harris Street
Charlotte, MI 48813

Location (Authorized Site) Being Inspected:

321 E. Harris
Charlotte, MI

Licensee Contact: S. J. Parikh, MD

Telephone No. (517) 543-1050

Priority: 3G

Program Code: 2120

Date of Last Inspection: 05/25/95

NMED/Event No(s): None

Date of This Inspection: 09/14/00

Type of Inspection:

() Announced

(X) Unannounced

(X) Routine

() Special

() Initial

Next Inspection Date 9/2005 () 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 past 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/

Tony S. Go

Date 9/19/00

Approved /RA/

Geoffrey Wright, Chief of M.I.B.

Date 9/21/00

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)

On 06/29/00, the licensee was given a "Clear" inspection; however, on 04/09/92, the licensee was cited on their survey instruments that were not capable detecting 2000 dpm. This violation was closed during 06/29/95 inspection.

There were no repeat violations on this current inspection. The licensee maintains a calibrated Ludlum-2000 well counter that is capable detecting 2000 dpm contaminations. The instrument was calibrated on 08/03/00 by MPC consultants.

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.)

The licensee personnel indicated that, the facility had not experienced events such as dose misadministrations or any accidents associated with the used of byproduct materials. 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)

**Matthew Rush, C.E.O.
Robert McElmory, V.P. Clinical Services
S. J. Parikh, M.D., RSO
Fran Barber, Director of Radiology**

Donald Crandall, CNMT
Mike Haman, CNMT
Kimberly Hubbrad, CNMT (Part Time Technologist)

The licensee is a 50-bed hospital performing about 20 nuclear medicine procedures per week. The licensee orders unit doses from Capital Pharmacy in Lansing, Michigan. The licensee had not submitted a QMP program in 1994; however, they may submit the program if they decided to use radiopharmaceutical doses greater than 33 uCi of iodine-131. To date, the license is limited to 10 CFR 35.100 and 200 programs. Since the last inspection, the licensee ordered I-123 doses for thyroid uptakes and scans. The licensee employs one part time and two N.M. technologists. The licensee authorizes 13 physicians under the license that also includes the RSO. The licensee does not perform Xe-133 studies at this time. Typically, the licensee's procedures are consisted of 60 percent of cardiac stress studies, and 40 percent of other diagnostic procedures. This licensee does not conduct human research studies with NRC licensed materials. The licensee retained James Botti of MPC consultants to perform quarterly audits since 1994. The licensee program has been expanding since 1998, and the department is opened only on weekdays.

2. PERSONNEL CONTACTED:

(Identify licensee personnel contacted during the inspection [including those individuals contacted by telephone].)

Matthew Rush, C.E.O.

Robert McElmory, V.P. Clinical Services

Fran Barber, Director of Radiology

Donald Crandall, CNMT

Mike Haman, CNMT

Dr. Parikh, RSO, he was on vacation during the week of inspection

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 nuclear medicine room. The radiation surveys at restricted and unrestricted areas including the hot lab inside the camera room indicated radiation levels near background of <.03 mR/hr (7nC/kg/hr). The highest readings were found at contact with the waste storage bin in the hot lab area due to TI-201 wastes, and near spent syringes behind a bio-shield at the hot lab table top. The highest reading at contact with waste containers was about 0.5 mR/hr (13 nC/kg/hr). The unrestricted areas at the nuclear medicine department's hallways did not indicate activity 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 nuclear medicine facility. These postings included NRC Form-3, "CAUTION: RADIOACTIVE MATERIAL" and "CAUTION RADIATION AREA" signs at the entrance to restricted areas. Containers such as the waste bin containing radioactive materials were appropriately labeled. There were no other postings at the unrestricted areas.

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 quarterly by the RSO and MPC consultants. Program reviews were found to be comprehensive. The results of reviews were presented quarterly to the members of Radiation Safety Committee (RSC). The record of the RSC meeting minutes were reviewed by the inspector from 11/27/96 through 05/25/00 and did not indicate problems with the licensee's safety equipments. A selective review of licensee audit records, survey records, and interviews with the staff demonstrated that the licensee's personnel were aware of the status of materials receipt, control, transfer, storage, use, and disposal of licensed material. The RSC records 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 02/09/98 through 09/13/00 showed that the licensee completed daily radiation level surveys on all the sites. These surveys indicated that there were no major contaminations. An interview of the staff indicated that they are aware on the licensee's spill procedures. The licensee's incident records did not indicate any spills 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 procedures. The annual training involves written tests administered by the MPC consultant. The annual training is conducted by MPC consultant 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 ICN. Dosimeters are exchanged on a monthly basis. A review of dosimetry reports from January 1998 to present indicated the following:

2000 TEDE = 117 mrem	SDE = 120 mrem
1999 TEDE = 60 mrem	SDE = 59 mrem
1998 TEDE = 37 mrem	SDE = 36 mrem

The licensee's dosimetry program was properly evaluated by the licensee's consultants and approved by the RSO. Currently the program assures that public doses are kept below the applicable regulatory limits.

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 overexposures.

The inspector verified through an interview that NRC-licensed materials have not been stolen or lost at the clients' facilities since the last inspection. All RAM materials (unit doses) are transported directly to the hot lab by the Capital's

pharmacy driver daily. The unit doses were shipped in Type-A packaging directly to the hot-lab each morning, and the hot lab was secured after the delivery. To date, no licensed materials were released nor removed from the restricted sites. 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 individuals authorized by 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 did not find radiopharmacy dispensing errors 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 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 Chief concerning this inspection was conducted on 09/18/00.

2. OTHER:

NONE