

SAFETY AND COMPLIANCE INSPECTION

1. LICENSEE

Emma L. Bitby MEDICAL CTR.
818 RIVERSIDE AVE.
ADRIANO, MI 49221

REPORT NUMBER(S)

2. REGIONAL OFFICE

REGION III
US NUCLEAR REGULATORY COMMISSION
801 WARRENVILLE ROAD
LISLE IL 60532-4351

3. DOCKET NUMBER(S)

030-02027

4. LICENSE NUMBER(S)

21-03194-01

5. DATE(S) OF INSPECTION

SEPT 14 2000

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	S. J. MURRAY	<i>[Signature]</i>	9/14/00

APPENDIX A

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Region 3

Inspection record No. 00-001

License No. 21-03194-01

Licensee (Name and Address):

Docket No. 030-02027

Emma L. Bixby Medical Center

818 Riverside Avenue

Adrian, MI 49221

Location (Authorized Site) Being Inspected:

As Above

Licensee Contact: **Marinus Van Ooyen, MD, RSO** Telephone No. **517-265-0900**

Priority: **G3** Program Code: **2120**

Date of Last Inspection: **5/24/96** NMED/Event No(s):

Date of This Inspection: **9/14/00**

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

Next Inspection Date **10/05** () Normal () Reduced (X) Extended

Justification for change in normal inspection frequency:

Overall good performer last two inspections.

Summary of Findings and Actions:

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

Inspector(s) **/RA/** Date **9/19/00**

(Sign Name)

S.J. Mulay, Radiation Specialist

Approved **/RA/** Date **9/21/00**

(Sign Name)

G. C. Wright, Chief, Nuclear Materials Inspection Branch

Issue Date: 04/24/00

-3-

2800/029, Appendix A

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)

No violations identified since 1992.

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.)

None per Mr. Kovach

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)

John Roberstad, CEO

Brian Herwig, VP

*** + Marinus Van Ooyen, MD, Medical Director, RSO**

John Bremer, Director of Radiology

+ Sharon Updike, Clinical Coordinator, Radiologist

* Chris Kovach, CNMT

Contacted during the inspection

* Attended Entrance Meeting

+ Attended Exit Meeting

SCOPE OF PROGRAM:

This 60 bed hospital performs about 120 procedures per month utilizing one full-time technologist and one cross-trained technologist. No generators. Unit doses are obtained from area pharmacy.

Approximately four thyroid therapies were performed in 1999 using less than 30 mCi iodine-131 in capsule form. No administrations for carcinoma are done. No strontium-89/iodine-131 treatments have occurred for 2000.

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

See section 1

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)

Hot Lab area: 0.1mr/hr (Maximum)

Imaging area: 0.02mr/hr

Unrestricted area: 0.02mr/hr

Bkg: 0.02mr/hr

Readings compared well with licensee results. NRC instrument used: Ludlum 2403, calibrated 12/16/99.

4. OTHER:
(e.g., posting and labeling)

Unit doses containing radioactive material were properly labeled and shielded prior to administration. Injection technique was successfully demonstrated during the inspection. The overall hot lab/imaging area was posted as required. No thefts, losses, incidents, or overexposures have occurred according to licensee representatives.

Dose calibrator constancy, linearity and accuracy were reviewed and were performed at the required frequencies. Readings did not vary by more than 10%. Geometry was not reviewed. Dose calibrator constancy check was observed during the inspection.

Sealed source inventory and leak tests are performed quarterly and each six months respectively by licensee's consultant with appropriate records maintained. Records for 6/16/00 were reviewed with all sources accounted for and no leakage noted.

The licensee performs daily surveys and weekly wipes as required. A record review did not indicate contamination. Area and package surveys were adequately demonstrated. Survey meter operational checks are also performed.

Licensee possesses a Ludlum-3 and one Eberline-520 survey meters each calibrated within the last twelve months. Response check with the NRC instrument revealed good comparison for the Ludlum 3 (Primary unit used by the licensee).

Doses are checked for accuracy in the dose calibrator prior to administration.

All necessary postings were properly displayed.

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)

The licensee contracts with an outside consultant (MPC) to perform quarterly program audits which adequately oversee program activities. RSC meeting minutes were reviewed for 3/30/00 and 6/16/00. Overall proper membership and good discussion content were evident for minutes reviewed. Licensee representatives indicated adequate RSO involvement and/or availability.

Overall management support is well implemented for program activities.

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)

Annual training is provided by the consultant (MPC). Interviews conducted with available staff, revealed an adequate level of understanding of emergency and material handling procedures and techniques.

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)

1999

2000 (thru August)

WB: 1144mR

693mR

Ext: 1000mR

613mR

Based on the above data, it appears that personal dosimetry is being worn during preparation and administration of licensed material. The technologist was counseled by the licensee to reduce the amount of time spent close to the patient in an attempt to reduce the individuals overall exposure.

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 hot lab and imaging areas were observed well surveilled and secured upon arrival and during the inspection. Overall security appears well maintained.

Unit dose receipt records were reviewed and revealed all appropriate visual inspections. Surveys and wipes are performed as required. Return shipments of used and unused unit doses were performed according to submitted procedures.

Radioactive waste is held for ten half-lives, surveyed to background levels and disposed in ordinary trash. The last disposal was on 8/14/99 with survey to background.

5 USE OF LICENSED MATERIAL ONLY AS AUTHORIZED YES ☒ NO ☐

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

Uses, types, quantity of licensed material as well as location of use were in accordance with submitted documentation. No problems were noted in this program area.

6. RADIOPHARMACEUTICAL ADMINISTRATIONS CONFORMING TO THE PHYSICIAN'S WRITTEN DIRECTIVES YES ☒ NO ☐

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

The licensee performs a limited radiopharmaceutical therapy program. According to licensee's records, no radiopharmaceutical therapies have been performed in 2000. Two written directives were reviewed for 1999, and contained all pertinent information, patient identification, etc. For this limited program area, QMP appeared to adequately implemented.

MPC performs a quarterly QMP audit with no problems noted to date.

No misadministrations were identified by the licensee, its medical consultant or through this inspection effort.

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)

Branch Chief

2. OTHER:
NA

END