

NOTE: All areas indicated in field notes are not required to be addressed during each inspection.

APPENDIX B
NUCLEAR MEDICINE INSPECTION FIELD NOTES
Region 3

Inspection Report No. 92001 License No. 13-03459-03
Licensee (name and address) Docket No. 030-31379
St. Mary Medical Center - Hobart
1500 South Lake Park Ave
Hobart, IN 46342
Licensee Contact Ken Vanderhyle Telephone No. 219-397-4664
Last Amendment No. 0 Date of Amendment 2/1/90

Priority : 2

Program Codes:

<input checked="" type="checkbox"/> 02110 - Broad Scope	<input checked="" type="checkbox"/> 02120 - Limited
<input checked="" type="checkbox"/> 02121 - Custom	<input checked="" type="checkbox"/> 02200 - Private Practice - Limited
<input checked="" type="checkbox"/> 02209 - In Vivo	<input checked="" type="checkbox"/> 02201 - Private Practice - Custom
<input checked="" type="checkbox"/> 02210 - Eye Applicator	<input checked="" type="checkbox"/> 02220 - Nuclear Medical Van
<input checked="" type="checkbox"/> 02400 - Veterinary	<input checked="" type="checkbox"/> 02410 - In Vitro
<input checked="" type="checkbox"/> 02500 - Pharmacy	<input checked="" type="checkbox"/> Other -

Date of Last Inspection 8/29/90

Date of This Inspection 4/23/92

Type of Inspection: ☒ Announced ☐ Unannounced
☒ Routine ☐ Special
☐ Initial ☒ Reinspection

Next Inspection Date. 6/94 ☒ Normal ☐ Reduced ☐ Extended

Summary of Findings and Action:

☒ No violations, Clear 591 or letter issued
☐ Violations, 591 or letter issued
☐ Action on Previous Violations

Inspector: James Mullane
(Signature)

Date 5/6/92

Approved: J.L. Semmes for WHS
(Signature)

Date 5/7/92

1. **ORGANIZATION**

a. Organizational structure meets license requirements [L/C]

[Signature] Y () N

Remarks: *Miktoz Triana, VP
 *Earl Masoz, M.S., Dir NRM
 *Tom Torabi, Ph.D., RSO
 *Ker Vandenbake, Regional Dir
 Beth Kaminski, RSO & Senior V.P.

b. Use by authorized individuals [35.22(b)(2)]

[Signature] Y () N

Remarks: *Mary Kroes, Senior Tech

c. Radiation Safety Committee

() N/A

- | | |
|------------------------------------------------|----------------------------|
| (1) Membership as specified in [35.22(a)(1)] | <i>[Signature]</i> Y () N |
| (2) Meetings held quarterly [35.22(a)(2)] | <i>[Signature]</i> Y () N |
| (3) Quorums established per [35.22(a)(3)] | <i>[Signature]</i> Y () N |
| (4) Has sufficient authority per [35.23] | <i>[Signature]</i> Y () N |
| (5) Committee reviews conducted per [35.22(b)] | <i>[Signature]</i> Y () N |
| (6) Record of Committee meetings [35.22(a)(4)] | <i>[Signature]</i> Y () N |

Remarks.

d. Radiation Safety Officer

- | | |
|------------------------------------------|----------------------------|
| (1) Appointed [35.21(a)] | <i>[Signature]</i> Y () N |
| (2) Fulfills duties per [35.21(b)] | <i>[Signature]</i> Y () N |
| (3) Has sufficient authority per [35.23] | <i>[Signature]</i> Y () N |

[Signature] Y () N

Remarks.

e. Visiting Authorized User

f) N/A

- (1) Has written permission [35.27(a)(1)] () Y () N
- (2) Copy of visitor's license on file [35.27(a)(2)] () Y () N
- (3) Performs only those procedures authorized on visitor's license [35.27(a)(3)] () Y () N
- (4) Uses material under licensee's license for sixty days per year or less [35.27(b)] () Y () N
- (5) Records maintained 3 years after last visit [35.27(c)] () Y () N

Remarks.

f. Mobile Nuclear Medicine Service

f) N/A

- (1) Licensee uses mobile nuclear medicine services [35.29] () Y () N
- (2) Licensee operates mobile nuclear medicine services [35.29, 35.80] () Y () N

Remarks.

2. INSPECTION HISTORY

() N/A - Initial inspection

- a. Last inspection conducted on 8/29/90
- b. Violations or deviations were identified *f*) Y () N
- c. Response letter or 591 dated 10/2/90
- d. Violations from Previous Inspection

<u>Requirement</u>	<u>Violation</u>	<u>Corrective Action Taken (Y/N)</u>	<u>Status</u>
1.) <u>Linearity</u>	<u>NOT Taken down To 10mCi</u>	<u>Yes</u>	<u>C</u>
2.) <u>Linearity</u>	<u>records NOT signed by RSO</u>	<u>Yes</u>	<u>C</u>
3.) <u>Constancy</u>	<u>NOT recorded 10 times</u>	<u>Yes</u>	<u>C</u>
4.) <u>Daily Survey</u>	<u>NOT recorded 7 times</u>	<u>Yes</u>	<u>C</u>

- e. Any previous violations not corrected
Explain.

() Y () N

3. SCOPE OF PROGRAM

- a. License has multiple authorized locations of use () Y () N
b. If so, list location(s) inspected () N/A

- c. List those individuals contacted during inspection

See Page B-2

*Indicates presence at exit meeting

- d. Briefly describe scope, including types of use involving byproduct material, frequency of use, staff size, etc.

This Moderate size program employs 3 FT NMTs who perform ~60 routine Procedures per week & ~6 Hypothyroid Tx per year OP only. Lung vents performed using Aerosol Only.

- e. Radiation safety program changes pursuant to [35.31]
f. Records of changes maintained [35.31(b)]

() Y () N () N/A
() Y () N () N/A

Remarks.

4. INTERNAL AUDITS OR INSPECTIONS

a. Audits or inspections are conducted

☒ Y () N () N/A

(1) Audits conducted by ASO

(2) Frequency semiannual

b. Audits are required by license condition

c. Records maintained

☒ Y ☒ N
☒ Y () N

Remarks.

5. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

a. Instructions to workers per [10 CFR 19.12]

☒ Y () N

Remarks.

b. Training program required [L/C]

() Y ☒ N () N/A

(1) Training program implemented

(2) Retraining program required

(3) Retraining program implemented

(4) Records maintained

☒ Y () N
☒ Y () N
☒ Y () N
☒ Y () N

Remarks.

c. Supervision of individuals by authorized user
in accordance with [35.25]

☒ Y () N

Remarks.

6. FACILITIES AND EQUIPMENT

a. Facilities as described in license application

~~()~~ Y () N

Remarks.

b. Areas for storage and use of RAM

(1) Adequate method used to prevent an unauthorized individual from entering restricted area

~~()~~ Y () N

(2) RAM is secured to prevent unauthorized removal from an unrestricted area [20.207]

~~()~~ Y () N

Remarks.

c. Dose calibrator

(1) Licensee possesses and uses dose calibrator(s) per [35.50(a)]

~~()~~ Y () N () N/A

(2) Constancy checked per [35.50(b)(1)]

~~()~~ Y () N

(3) Linearity tested per [35.50(b)(2)]

~~()~~ Y () N

(4) Accuracy tested per [35.50(b)(3)]

~~()~~ Y () N

(5) Geometry dependence tested per [35.50(b)(4)]

~~()~~ Y () N

(6) Readings mathematically corrected if linearity error is greater than 10% [35.50(d)]

~~()~~ Y () N

(7) Records maintained [35.50(e)]

~~()~~ Y () N

(8) RSO signs linearity, accuracy and geometry dependence tests [35.50(f)]

~~()~~ Y () N

Remarks.

d. Survey instruments

- (1) Appropriate operable survey instruments possessed per [35.120,220,320,420] or available per [35.520]
- (2) Calibration performed as required in [35.51]
- (3) Records maintained [35.51(d)]
- (4) Proper operation checked with check source per [35.51(c)]

[Signature] Y () N () N/A
[Signature] Y () N
[Signature] Y () N
[Signature] Y () N

Remarks.

- e. Syringes containing RAM properly labeled and shielded unless contraindicated per [35.60]

[Signature] Y () N
[Signature] Y () N

- f. Vials containing RAM properly labeled and shielded per [35.61]

Remarks.

7. RADIOLOGICAL PROTECTION PROCEDURES

- a. Radioactive materials used in accordance with current procedures [L/C]

[Signature] Y () N

Remarks.

b. Individual understanding of current procedures is adequate

- (1) in general rules for safe use of RAM
- (2) in emergency procedures

[Signature] Y () N
Y () N

Remarks.

8. MATERIALS

a. Licensee uses unit doses

Synca

[Signature] Y () N
() Y () N

b. Licensee uses generators

c. Licensee possesses sealed sources or brachytherapy sources per [35.59]

[Signature] Y () N

d. Isotope, chemical form, quantity and use as authorized [L/C, 31.11, 35.100, 200, 300, 400, 500]

✓ ✓ ✓ ✓ ✓

[Signature] Y () N

Remarks.

e. Molybdenum-99 breakthrough

[Signature] N/A

(1) Test performed per [35.204(b)]

(2) Records maintained per [35.204(c)]

() Y () N
() Y () N

Remarks.

f. Leak tests and Inventory

- | | |
|-------------------------------------------------------------------------------------|----------------------|
| (1) Leak tests performed on sealed sources and brachytherapy sources per [35.59(b)] | / Y () N |
| (2) Inventory of sealed sources and brachytherapy sources per [35.59(g)] | / Y () N |
| (3) Leak tests records in microcuries | / Y () N |
| (4) Leak test/inventory records signed by RSO | / Y () N |
| (5) Records maintained of leak tests and inventories for 5 years | / Y () N |

Remarks. Inspector verified the presence of 11 Cs-137 brachytherapy sources.

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

- a. Describe how packages are received and by whom: () N/A

Received by security & placed in Hot Lab

- | | |
|---------------------------------------------------------------------------------|----------------------|
| b. Opening procedures established and followed [20.205(d)] | / Y () N |
| c. Incoming packages wiped per [20.205(b)] | / Y () N |
| d. Incoming packages surveyed per [20.205(c)] | / Y () N |
| e. Transfer(s) performed per [30.41] | / Y () N |
| f. Records of surveys and receipt/transfer maintained per [20.401(b) and 30.51] | / Y () N |

Remarks.

10. AREA SURVEYS

() N/A

- a. Ambient exposure rate surveys conducted per [35.70(a),(b),(c)]
- b. Contamination surveys conducted per [35.70(e),(f)]
- c. Trigger levels established [35.70(d), (g)]
- d. Exposure rate survey records in mR/hr
- e. Contamination survey records in dpm/100 cm²
- f. Records maintained per [35.70(h)]

~~()~~ Y () N
~~()~~ Y () N
~~()~~ Y () N
~~()~~ Y () N
~~()~~ Y () N
~~()~~ Y () N

Remarks.

11. RADIOPHARMACEUTICAL THERAPY

Thyroid Only

- a. Licensee provides safety instruction [35.310] and implements safety precautions [35.315] or equivalents [L/C]
- b. Patient room contamination surveys per [35.315]
- c. Release of patients containing radiopharmaceuticals meets [35.75]
- d. Thyroid burden measured on individuals involved in dose administrations [35.315(a)(8)]
- e. Records maintained

() Y () N
 () Y () N
 () Y () N
 () Y () N
 () Y () N

Remarks.

12. BRACHYTHERAPY

None performed until the order suspending therapy activity

- a. Licensee provides safety instruction [35.410] and implements safety precautions [35.415] or equivalent [L/C]
- b. Patient surveys performed per [35.406]
- c. Release of patients containing permanent implants meets [35.75]
- d. Release of patients treated with temporary implants meets [35.404]

() Y () N
 () Y () N
 () Y () N
 () Y () N

- | | | |
|----|------------------------------------------------------------------------------------------|------------------------|
| e. | Brachytherapy sources inventoried per [35.4] | () Y () N |
| f. | Brachytherapy source storage area surveyed quarterly and record signed by RSO [35.59(h)] | () Y () N |
| g. | Records maintained | () Y () N |

Remarks.

13. PERSONNEL RADIATION PROTECTION - EXTERNAL

- a. Film or TLD supplier Landauer Frequency Mo
- b. Supplier is NVLAP - approved (A) Y () N
- c. Reports reviewed by R50 Frequency Mo
- d. NRC inspector reviewed personnel monitoring records for period 1990 to 3/92
- e. NRC forms or equivalent
- (1) NRC-4: () Y () N Complete: () Y () N () N/A
- (2) NRC-5: (A) Y () N Complete: (A) Y () N () N/A
- [20.401(a)]
- f. List maximum ^{annual} exposures (millirem): G1 = 170 mRem
W3 = 1310 mRem
- g. Licensee has implemented an ALARA program [35.20] (A) Y () N

Remarks.

14. PERSONNEL RADIATION PROTECTION - INTERNAL

- a. Potential for exposure of individuals to airborne RAM exists () Y () N
- b. Monitoring for airborne radioactivity conducted [20.201(b) to meet 20.103, 35.90, and 35.205] () Y () N

- c. Records maintained [20.401, 35.205(d), and C] ☐ Y ☐ N
- d. Bioassay program implemented as described in correspondence with NRC ☐ Y ☐ N
- e. Radioactive gases
- (1) Clearance time and safety procedures are posted [35.205(d)] ☐ Y ☐ N
- (2) Reusable collection systems checked monthly ☐ Y ☐ N
- (3) Ventilation rates checked each six months for negative pressure [35.205(e)] ☐ Y ☐ N

Remarks.

15. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

- a. RAM in effluents to unrestricted areas ☐ Y ☒ N
- b. Release in accordance with regulatory limits [20.106(a)] ☐ Y ☐ N

Remarks.

- c. Describe waste disposal method(s) - solid and liquid:

*Waste sent back to Lincoln
+ miscell waste held for decay.*

- d. If LLW is stored because access to a burial site has been denied, answer (1), (2), and (3) below:

- (1) Adequate control of waste in storage is maintained ☐ Y ☐ N
- (2) Package is labeled and package integrity is adequately maintained ☐ Y ☐ N
- (3) Adequate records of surveys and material accountability are maintained ☐ Y ☐ N

- e. Disposal of waste in accordance with regulatory requirements [20.301 and 35.92] ☐ Y ☐ N
- f. Decay-in-storage waste disposed per [35.92] ☐ Y ☐ N
- g. Records maintained [20.401(b) and 35.92(b)] ☐ Y ☐ N

Remarks.

16. NOTIFICATION: AND REPORTS

- a. Licensee in compliance with [19.13]
(reports to individuals)
- b. Licensee in compliance with [20.402]
(theft or loss)
- c. Licensee in compliance with [20.403]
(incidents)
- d. Licensee in compliance with [20.405]
(overexposures)

() Y () N () N/A
() Y () N () None
() Y () N () None
() Y () N () None

Remarks.

17. MISADMINISTRATIONS

- a. Misadministrations have occurred
 - (1) Diagnostic
 - (2) Therapeutic
- b. Licensee in compliance with reporting
therapeutic misadministrations
[35.33(a),(b)]
- c. Licensee in compliance with reporting
diagnostic misadministrations, if required
[35.33(c)]
- d. Appropriate action taken to prevent recurrence
- e. Records maintained [35.33(d)]

() Y () N
() Y () N
() Y () N
() Y () N
() Y () N
() Y () N

Remarks.

18. POSTING AND LABELING

- a. NRC-3 "Notice to Workers" posted
- b. Parts 19, 20, and 21 and license are posted or a notice indicating where documents can be examined is posted [19.11, 21.6]
- c. Other posting and labeling per [20.203]

☒ Y () N
☒ Y () N
☒ Y () N

Remarks.

19. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 171-189)

- a. Licensee makes shipments of RAM
- b. If so, describe shipment content and method:

() Y ☒ N

- c. Licensee is aware of 10 CFR 61 requirements
- d. Licensee classifies and characterizes waste
- e. Shipments

() Y () N () N/A

() Y () N () N/A

- (1) Authorized packages used [173.415, 416]
- (2) Package type used _____
- (3) For DOT-7A packages, performance test record on file [173.415(a)]
- (4) For special form sources, performance test record on file [173.476(a)]
- (5) Packages properly labeled [172.403, 173.441]
- (6) Packages properly marked [173.200]
- (7) Proper shipping papers prepared and used [172.200-204]

() Y () N () N/A

() Y () N () N/A

() Y () N () N/A

() Y () N () N/A
() Y () N () N/A

() Y () N () N/A

Remarks.

f. Licensee must return shipments of radiopharmacy doses

(X) Y () N () N/A

- (1) If YES, licensee assumes responsibility of all shipper requirements
- (2) If NO, describe arrangements made between licensee and radiopharmacy as to performance of shipper responsibilities:

(X) Y () N

20. RECORDKEEPING FOR DECOMMISSIONING

- a. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)]
- b. Records include all information outlined in [30.35(g)]

() Y () N

() Y () N

Remarks.

21. INDEPENDENT MEASUREMENTS

- a. Survey instrument used Letex
- b. NRC Serial No. 033482
- c. Last date of calibration 11/11/91
- d. Inspector's measurements were compared to licensee's
- e. Describe the type and results of measurements:

(X) Y () N

Side by side 1 m r/hy
unstructured areas checked < 2 m r/hy.

22. BULLETINS AND INFORMATION NOTICES

- a. Bulletins, Information Notices, etc., received by the licensee () Y () N
b. Licensee took appropriate action in response to Bulletins, INs, etc. () Y () N

Remarks.

23. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

24. LIST OF VIOLATIONS

25. PERFORMANCE EVALUATION FACTORS

Licensee
(name &
location)

St. Mary Medical Center
Hobart, IN

Hobart
Inspector

Inspection Date

Mullauer
4/23/92

- a. Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight
- b. RSO too busy with other assignments
- c. Insufficient staffing
- d. Radiation Safety Committee fails to meet or functions inadequately
- e. Inadequate consulting services or inadequate audits

() Y N

() Y N

() Y N

() Y N

() Y N

Remarks (consider above assessment and/or other pertinent PEFs):

Regional follow-up on above PEFs citations:

DO. Torabi
4321 Fir Street
East Chicago, IN 46312
(219) 397-4664

Lakeshore Health System

St. Catherine Hospital
East Chicago, IN


St. Mary Medical Center
Gary and Hobart, IN

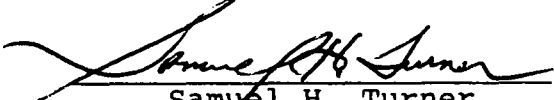
April 26, 1991


Reference: 10CFR35.23; August, 1990

We, Lakeshore Administration, give sufficient authority and various management responsibilities to our Radiation Safety Officer, Dr. Tom Torabi, for the following items:

1. To identify radiation safety problems, hazards, violations, or any other problem which may be in violation of our NRC license, NRC regulations, and safety policies.
2. To initiate, recommend, and provide corrective action for problems.
3. To verify implementation of corrective actions.
4. To inform administration, radiation safety committee, and any other applicable parties or regulating agencies about problems or seek advise from the above mentioned.
5. To perform all duties as outlined in the job description and statement of duties to the best of his abilities, including maintaining the ALARA program.
6. To assure the hospital that quality, and accuracy of work is being done in departments under the surveillance of the Radiation Safety Officer for providing quality and appropriate patient care.


Beth Kaminski
Chief Operating Officer
St. Mary Medical Center/H


Samuel H. Turner
Chief Operating Officer
St. Mary Medical Center/G


Jack Bryan
Chief Operating Officer
St. Catherine Hospital