MEDICAL

LICENSE FILE NO: 29-20597-01
ATTACHED

DOCKET No. (s) 030-19662 [ ] Appendix A [X] Appendix B [ ] Appendix C

INSPECTION REPORT NO. 030-19662/9001 LICENSEE CONTACT: Barbara Matthews
Name: St. Mary's Hospital TELEPHONE NO.:
Address: 135 S. Center Street
Orange, NJ 07051

LICENSE NO: 29-20597-01 PRIORITY: 3 6 Program Code: 02120
PRIORITY: Program Code:
PRIORITY: Program Code:

INSPECTION DATE (s): 10-23-90 TYPE OF INSPECTION: [ ] SPECIAL [ ] ANNOUNCED
[X] ROUTINE [X] UNANNOUNCED
[X] DAYSHIFT [ ] OTHER

SUMMARY OF FINDINGS AND ACTION

[X] NO NONCOMPLIANCE, CLEAR 591 ISSUED
[ ] ACTION ON PREVIOUS NONCOMPLIANCE, APPENDIX B
[ ] NO NONCOMPLIANCE, LETTER
[ ] NONCOMPLIANCE, 591 ISSUED
[ ] NONCOMPLIANCE, APPENDIX A
[ ] SUPPLEMENTAL INFO, APPENDIX C

RECOMMENDATIONS
SEE APPENDIX C

[ ] CHANGE PROGRAM CODE [ ] CHANGE PRIORITY TO:

[X] NEXT INSPECTION DATE: October 1993

PERSONS CONTACTED

* Barbara Matthews
* Dr. Brennan
* Dr. Mary Mastrella, RSO
* Mr. Michael Schutsky, D.C.

INSPECTOR: Betty Ullrich 10/29/90 Mark Dalton 10-29-90
APPROVED: 10/30/90

REGION I Form 198-C
(June '88)

B-12

1. ORGANIZATION

a. Organizational structure meets license requirements. (Y) Yes ( ) No [L/C]
Remarks.

b. Use supervised by authorized individuals. (Y) Yes ( ) No [35.22(b)(2)]
Remarks.

c. Radiation Safety Committee meets at quarterly intervals.
(X) Yes ( ) No

(1) Membership in accordance with 35.22(a)(1)] (X) Yes ( ) No
Remarks.

(2) Record of Committee meetings. (X) Yes ( ) No [35.22(a)(4)]
Remarks.

(3) Consultants. (X) Yes ( ) No
Remarks.
currently using Bio-Med

e. Licensee uses the services of a visiting authorized user.
( ) Yes (X) No [35.27(a)]

(1) Licensee has a copy of visiting authorized user license.
( ) Yes ( ) No [35.27(a)(2)]

(2) License has records (maintained for 2 years) of visiting authorized users last visit. ( ) Yes ( ) No [35.37(c)]

f. License utilizes mobile nuclear medicine services.
( ) Yes (X) No [35.29]

g. Licensee delegates RSO sufficient authority, organizational freedom, and management prerogative. (X) Yes ( ) No

h. Appropriate review by Committee in accordance with 35.22(b).
( ) Yes ( ) No

2. INSPECTION HISTORY

Violations or deviations noted during last inspection conducted on 10-6-87
( ) Yes ( ) No.

Response letter dated 12-18-87
(See Appendix B for details)

3. SCOPE OF PROGRAM

Briefly list medical procedures and their frequency.

Only treating 1-2 patients per week, only Tc-99m used at this time. Typically do renal imaging or occ. bone, liver, or brain. No aerosols used for more than a year. Hospital program is "ambulatory care" only - no inpatients at this time.

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by license condition. ( ) Yes (X) No ( ) N/A

b. Investigations or inspections conducted. (X) Yes ( ) No [35.21(a) and (b)(2)]
Remarks.

Consultant performs audit as well as other contracted services.

c. Records maintained. (/) Yes ( ) No [35.21(b)(2)(xi)]
Remarks.

5. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

a. License referenced training program.

(1) Training program implemented. (X) Yes ( ) No
Remarks.

Currently only one Nuc Med Tech.

(2) Retraining program implemented. (X) Yes ( ) No
Remarks.

5. (cont'd)

b. Instruction to workers in accordance with 10 CFR 19.12.
(X) Yes ( ) No
Remarks.

*c. Describe the QA program to mitigate therapeutic misadministrations. NA

(1) Have secondary checks of the dose calculations been done?

( ) Yes ( ) No

(2) Do the second party checks of the dose calculations provide assurance that the final treatment plan will provide the dose prescribed on the patient chart? ( ) Yes ( ) No

(3) Do technologists consult with the doctor if the prescription or other orders are unclear? ( ) Yes ( ) No
Remarks.

d. Followup on therapy or serious diagnostic misadministrations NA

(1) 10 CFR 35.43 properly implemented? ( ) Yes ( ) No

(2) Was proper medical care given for the patient pursuant to the NRC medical consultant recommendations? ( ) Yes ( ) No

(3) Were appropriate actions implemented to prevent recurrence? ( ) Yes ( ) No

(4) Were the technologist and dosimetrist made aware of these actions? ( ) Yes (No)

(5) Do the licensee's QA/QC procedures address these actions to prevent recurrence? ( ) Yes ( ) No
Remarks.

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Radiation Safety program changes reviewed. (Exception to changes without license amendment may be found in 35.13 and 35.606.)
(X) Yes ( ) No

*Inspect when QA rule becomes final.

6. (cont'd)

b. Records of changes in procedures reviewed. (X) Yes ( ) No [35.31(b)]
Remarks.

c. Radioactive materials used in accordance with current procedures.
(X) Yes ( ) No [35.21(b)(2)]
Remarks.

(1) Describe individuals understanding of current procedures.

very good

(2) Examples of key procedures:
(a) ordering and accepting packages of RAM OL
(b) general rules for safe use of RAM OL
(c) emergency procedures OL
(d) survey procedures OL
(e) handling of volatile RAM (e.g., Xe-133, I-131) OL
(f) precautions for use of RAM (sealed and unsealed) for therapy NA
(g) emergency procedures posted? yes
(h) do licensee personnel understand emergency procedures? Yes
(i) safety procedures for patient therapy in accordance with 35.315 and 35.415 NA

7. MATERIALS, FACILITIES AND INSTRUMENTS

a. Facilities as described in license application. (X) Yes ( ) No
Remarks.

b. Isotope, chemical form, quantity and use as authorized.
(X) Yes ( ) No [L/C]
Remarks.

Unit does only

c. Syringes containing radioactive material properly labeled and shielded unless contraindicated. (X) Yes ( ) No [35.60(a)(b)(c)]

d. Vials containing radioactive material properly labeled and shielded.
( ) Yes ( ) No [35.61(a)(b)] NA

7. (cont'd)

e. Tests required by regulations. NA

(1) molybdenum-99 breakthrough. ( ) Yes ( ) No [35.204(b)] NA
(2) performed as required. ( ) Yes ( ) No [35.204(a)] NA
(3) records maintained. ( ) Yes ( ) No [35.204(c)] NA
Remarks.

(4) Leak tests. (X) Yes ( ) No

(5) Leak tests performed as required. (X) Yes ( ) No [35.59(b)]
Dates and Remarks.

f. Inventory of sealed sources.

(1) Inventory of Group VI sources. ( ) Yes ( ) No [35.59(g)] NA
Dates:

(2) Inventory of calibration sources. (Y) Yes ( ) No [35.59(g)]
Dates: 1/89 3/89 6/89 12/89
2/90 5/90 8/90

g. Areas for storage and use of radioactive materials.

(1) Method used to prevent an unauthorized individual lock door

(2) Radioactive material secured to prevent unauthorized removal from an unrestricted area. (X) Yes ( ) No [20.207]

Remarks.

(3) Area wipe tested? (X) Yes ( ) No
Remarks.

h. Instrumentation.

(1) Operable survey instruments are as described or equivalent to those described in license application. (X) Yes ( ) No
[35.120, 220, 320, 420]
Remarks.

Victoreen 498

7. (cont'd)

(2) Capability of radiation survey instruments is adequate for program.
(y) Yes ( ) No
Remarks.
checked operation - OK

(3) Calibration of survey instruments required. (y) Yes ( ) No

(a) Performed as required. (X) Yes ( ) No [35.50]
Dates and Remarks.
2/86 2/89
2/87 2/90
2/88

(4) Records of calibration maintained for 2 years. [35.50(e)]
(X) Yes ( ) No

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

Receipt of incoming packages during "off-duty" hours by whom? security

(a) Where stored? Security? [L/C] stored in Hot Lab

(b) Survey of incoming packages. (X) Yes ( ) No [20.205(b)(1)]
Remarks.

(1) Record of survey. (X) Yes ( ) No [20.401(b)]
Remarks.

(c) Procedure for opening packages. (X) Yes ( ) No [20.205(d)]
Remarks.

(d) Returned licensed material transferred in accordance with 10 CFR 30.41.
(X) Yes ( ) No
Remarks.
~~Uranium, Lab~~ mrn

8. (cont'd)

(e) Records of receipt and transfer maintained. (X) Yes ( ) No [30.51]
Remarks.

9. PERSONNEL RADIATION PROTECTION - EXTERNAL
(Obtain information regarding whole body and extremity monitors)

a. Film or TLD badge supplier Landauer Frequency M

b. Reports reviewed by RSO? _____ Others _____?
Frequency _____
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period 12-15-87 to 7-4-90

d. NRC forms or equivalent.

(1) NRC-4: ( ) Yes ( ) No Complete: ( ) Yes ( ) No
Necessary ( ) Yes ( ) No

(2) NRC-5: ( ) Yes ( ) No Complete: ( ) Yes ( ) No
[20.401(a)]
Remarks.

e. Maximum quarterly whole-body exposure. 60

f. Maximum quarterly extremity exposure. 250

g. Licensee has implemented an ALARA program. ( ) Yes (X) No
[35.50] [see Procedure No. 83822, "Radiation Protection]
Remarks.

h. Radiation survey of unrestricted areas. (X) Yes ( ) No
(20.201(b) to show compliance with 20.105(b)) [35.315(a)(4)];
[35.415(a)(4)]
Remarks.

9. (cont'd)

(1) Record of surveys maintained. (✓) Yes ( ) No [20.401(b) to show compliance with 20.105(b)]
Remarks.

i. Radiation survey of storage and use areas:

(1) Quarterly survey brachytherapy source storage. ( ) Yes ( ) No NA [35.59(h)]

(2) Temporary implant patient release survey. ( ) Yes ( ) No NA [35.404(a)]

(3) Radiopharmaceutical and permanent implant patient release survey. NA ( ) Yes ( ) No [35.75]

(4) Radiopharmaceutical therapy room contamination survey. NA ( ) Yes ( ) No [35.315(a)(5) and (7)]

(5) Patient survey upon implant. ( ) Yes ( ) No [35.406(c)]

(6) Radiopharmaceutical storage and laboratory use areas. (✓) Yes ( ) No [35.70]
Remarks.

j. Record of survey maintained. (✓) Yes ( ) No [35.70(h)]
Remarks.

k. Inventory of brachytherapy sources after use. ( ) Yes ( ) No NA [35.406]
Remarks.

l. Records maintained. (✓) Yes ( ) No [35.59(g)]; [35.406]

m. Dose calibrator calibration and checks performed as follows:
Constancy (✓) Yes ( ) No Accuracy (✓) Yes ( ) No
Linearity (✓) Yes ( ) No Geometric dependence (✓) Yes ( ) No
[35.50] → 4/89

Calibrated used 1987, 1988, 1989

Decay method 1990

10. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive material exists.
( ) Yes (X) No
Remarks.

b. Monitoring for airborne radioactivity conducted. ( ) Yes (X) No
[20.201(b) to show compliance with all sections of 20.103 and 35.90]
Remarks.

(1) Records of monitoring maintained. ( ) Yes ( ) No N/A
[20.401(b) or L/C]
Remarks.

Xe-133 has not been used for several years. However, clearance time is calculated, and monthly check of unit is performed.

c. Bioassay program implemented as described in correspondence with NRC.
(X) Yes ( ) No [35.315(a)(8)]

d. Control of airborne radioactivity in accordance with 35.205.
(X) Yes ( ) No

11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. Radioactivity in effluents to unrestricted areas. ( ) Yes (X) No

b. Release in accordance with regulatory limits. ( ) Yes ( ) No N/A
[20.106(a)]
Remarks.

c. State solid waste disposal method. } 1) decay-in-storage
d. State liquid waste disposal method. } 2) return to supplier

11. (cont'd)

e. Disposal of solid and liquid waste in accordance with regulatory requirements (decay in storage). (Y) Yes ( ) No [35.92(a)]
Remarks.

(1) Records of disposal. (Y) Yes ( ) No [35.92(b)]
Remarks.

f. Survey of waste prior to disposal. ( ) Yes ( ) No
[20.201(b) to show compliance with 20.301 - 35.92(a)(2)]
Remarks.

(1) Records of survey maintained. (Y) Yes ( ) No [20.401(b)]
Remarks.

12. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10 CFR 19.13 (reports to individuals).
(Y) Yes ( ) No [19.13] NA
Remarks.

b. Licensee in compliance with 10 CFR 20.405 (overexposures).
(Y) Yes ( ) No [20.405(a)] NA
Remarks.

c. Licensee in compliance with 10 CFR 20.403 (incidents).
(Y) Yes ( ) No [20.403] NA
Remarks.

12. (cont'd)

d. Licensee in compliance with 10 CFR 20.402 (theft or loss). (X) Yes ( ) No [20.402(a) or (b)]
Remarks. NA

e. Licensee in compliance with reporting therapeutic misadministrations and taking corrective action. (X) Yes ( ) No [35.33(a)(b)(d)]
Remarks. NA

f. License in compliance with reporting diagnostic misadministrations and taking corrective action as needed under conditions set forth in 10 CFR 35.33(c).
(X) Yes ( ) No
Remarks. NA

13. POSTING OF NOTICES

Notices to workers posted. (X) Yes ( ) No [19.11(a), (b), or (c)]
Remarks.

14. CONFIRMATORY MEASUREMENTS

a. Measurements made by inspector. (X) Yes ( ) No

b. Survey instrument and probe Victoreen Model 3 w/ thin end GM
NRC Serial No. 07766

c. Describe type and results of measurements and compare with licensee's measurements.

15. INDEPENDENT MEASUREMENTS

a. Measurements made by inspector. (X) Yes ( ) No

b. Survey instrument _____
NRC Serial No. _____

c. Describe type and results of measurements.

Hot lab, camera room, office area, halls, cold lab: All background (<0.05 mR/h) except behind shielded area where bone was stored.

16. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203.
(X) Yes ( ) No [20.203]
Remarks.

17. LICENSE CONDITIONS

a. All license conditions reviewed during inspection. (X) Yes ( ) No

b. Activities were conducted in accordance with license conditions, except as noted elsewhere in this report. (X) Yes ( ) No
Remarks:

18. BULLETINS AND INFORMATION NOTICES

a. Bulletins and Information Notices issued during current year.
List: NI

b. Bulletins and Information Notices received by licensee. ( ) Yes ( ) No
Remarks.

c. Licensee took appropriate action in response to Bulletins and Information Notices. ( ) Yes ( ) No
Remarks.

19. TRANSPORTATION (10 CFR 71.5a and 49 CFR 171-178)

	Yes	Violation?
a. License makes shipments of RAM? If "Yes", complete the following items.	( )	( ) NO

b. Such shipments consisted of:
( ) radwaste
( ) sources/products
( ) other _____

19. (cont'd)

c. For radwaste, shipments are:
( ) by licensee, using common carrier
( ) through Radwaste Broker
name of Broker _____

d. Licensee is aware of 10 CFR 61: Radwaste requirements for generators?	( )	( )
Licensee has classified and characterized its radwaste? (20.311(d))	( )	( )
e. For shipments: Licensee uses authorized packages? [(173.415-16)]	( )	( )
Package type used. _____		
For DOT-7A, licensee has performance test records on file? [173.415(a))]	( )	( )
For special form sources, licensee has performance tests records on file for each source design? [(173.47(a))]	( )	( )
Packages are properly labeled? [172.403)]	( )	( )
[173.441)]	( )	( )
Packages are properly marked? [172.200)]	( )	( )
Proper shipping papers are prepared for each shipment? [172.203(d))]	( )	( )
Remarks.		
f. Does licensee make return shipments of radiopharmacy doses? (If Yes, does licensee assume responsibility for all shipper requirements?) (If No, what arrangements/understanding have been made between licensee and radiopharmacy as to performance of shipper responsibilities?) (Describe)	(X)	( )
Remarks.		

licensee is shipper — performs survey and label package in accordance w/ supplier direction

20. ITEMS OF NONCOMPLIANCE

None

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

INSPECTION REPORT NUMBER _____

APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

LICENSEE: _____ License No. _____

Reference	Basis for noncompliance
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	

INSPECTION REPORT NUMBER

APPENDIX B - LICENSEE ACTIONS ON PREVIOUS INSPECTION FINDINGS

Licensee: St. Mary's Hospital License No.: 29-20597-01

Identification and summary of action taken			Status
Report No.: 87-001	Type n/c:	Describe:	
Action taken: Effluent factor calculated. All results were converted to and recorded in "DPM". Consultant reviews, and checks calibr. facts.			OPEN CLOSED
Report No.:	Type n/c:	Describe:	
Action taken:			OPEN CLOSED
Report No.:	Type n/c:	Describe:	
Action taken:			OPEN CLOSED
Report No.:	Type n/c:	Describe:	
Action taken:			OPEN CLOSED
Report No.:	Type n/c:	Describe:	
Action taken:			OPEN CLOSED
Report No.:	Type n/c:	Describe:	
Action taken:			OPEN CLOSED

INSPECTION REPORT NUMBER _____

APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: _____ License No.: _____

( ) Uncorrected/repeated noncompliance

( ) Unusual occurrence, conditions, etc.

( ) Basis for change of Category or Priority

( ) Unresolved items

( ) Inspector's comments