APPENDIX B

NUCLEAR MEDICINE INSPECTION FIELD NOTES*

Region I

Inspection Report No. ..... License No. 29-20597-01
Licensee (Name and Address): Docket No. 030-19962

St. Mary's Hospital
135 Center St. South
Orange, NJ

Licensee Contact: Gloria Locket Telephone No. (201) 266 3063
Last Amendment No. 03 Date of Amendment 9-30-92
Priority:

Program Code:

- ( ) 02110 - Broad Scope
- ( ) 02121 - Custom
- ( ) 02209 - In Vivo
- ( ) 02210 - Eye Applicator
- ( ) 02230 - HDR
- ( ) 02400 - Veterinary
- (✓) 02120 - Limited
- ( ) 02200 - Private Practice - Limited
- ( ) 02201 - Private Practice - Custom
- ( ) 02220 - Nuclear Medical Van
- ( ) 02410 - In Vitro
- ( ) Other -

Date of Last Inspection 10-23-90

Date of This Inspection 6-2-93

Type of Inspection:

- ( ) Announced
- (✓) Unannounced
- (✓) Routine
- ( ) Special
- ( ) Initial
- ( ) Reinspection

Next Inspection Date 6-95 (✓) 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: ..... Date: 6-21-93
(Signature)

Approved: ..... Date: .....
(Signature)

B-10

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

1. ORGANIZATION

a. Organizational structure meets license requirements (L/C) (✓) Y ( ) N

Remarks: Very small Hospital run by the Archdioces of Newark. Bertha Peter-Stokes is the administrator. Gloria Locket is Vice President of Operations. Currently licensed activities are suspended (last patient scans in July 1992). Only outpatients are treated.

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

Remarks: There is only one authorized user who practices at another hospital unit of this organization (under a different License). There are no immediate plans to restart the NM program but the licensee want to keep the Licens

c. Radiation Safety Committee ( ) N/A

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

Remarks: No records of a meeting held in the 3rd Quarter of 1992 In one meeting held on March 4, 1992, there was no indication that the RSO also attended that meeting.

N/C

d. Radiation Safety Officer

(1) Appointed [35.21(a)]	(✓) Y ( ) N
(2) Fulfills duties per [35.21(b)]	(✓) Y ( ) N
(3) Has sufficient authority per [35.23]	(✓) Y ( ) N

Remarks: Licensee changed RSO on July 9, 1992 (NRC notified) Again another RSO was put on the license in Sept. 1992 Dr. Pablo Roy is the current RSO and the only authorized user.

e. Visiting authorized user (✓) 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: .....

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f. Mobile Nuclear Medicine Service (✓) 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: .....

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2. Inspection History ( ) N/A - Initial Inspection

a. Last inspection conducted on October 23, 1990

b. Violations or deviations were identified ( ) Y (✓) N

c. Response letter or 591 dated October 23, 1990

d. Violations from Previous Inspection:

Requirement	Violation	Corrective Action Taken (Y/N)	Status
	NONE		

e. Any previous violations not corrected ( ) Y (✓) N

Explain: ...No...previous...violations.....

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3. SCOPE OF PROGRAM

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

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c. List those individuals contacted during inspection:

Michael Teeters (Consultant Via phone).....
*Gloria Locket, V.P.....
*Bertha Peters-Locke Stokes, Administrator.....
*Dr. Francis McGinny, Medical Director.....

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*Indicates presence at exit meeting

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

Program suspended in July 1992 because of lack of patients. Prior to July, 1992, there were three authorized users. Tc-99m, I-123, Tl-201 and Ga-67 and occasionally I-131 was used. (Only two dosages of I-131 given in 1992) w/ 2 patients per day for different scans.....

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e. Radiation safety changes pursuant to [35.31] (✓) Y ( ) N ( )N/A
f. Records of changes maintained [35.31(b)] (✓) Y ( ) N ( )N/A

Remarks: See item 1.d.....

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4. INTERNAL AUDITS OR INSPECTIONS

a. Audits or inspections are conducted (✓) Y ( ) N ( )N/A

(1) Audits conducted by Consultant (Michael Tecker).

(2) Frequency ....Annual.....

b. Audits are required by license condition (✓) Y ( ) N

c. Records maintained (✓) Y ( ) N

Remarks.....

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5. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

a. Instructions to workers per [10 CFR 19.12] (✓) Y ( ) N

Remarks .....

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b. Training program required [L/C] (✓) Y ( ) N ( )N/A

(1) Training program implemented (✓) Y ( ) N

(2) Retraining program required (✓) Y ( ) N

(3) Retraining program implemented (✓) Y ( ) N

(4) Records maintained (✓) Y ( ) N

Remarks .....

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c. Supervision of individuals by authorized user in accordance with [35.25] (✓) Y ( ) N

Remarks .....

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6. FACILITIES AND EQUIPMENT

a. Facilities as described in license application (✓Y ( ) N

Remarks .....

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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 There were no radiopharmaceuticals stored in the hot lab. Only ~~sources~~ sealed sources used for QA of the dose calibrator. No detectable contamination of hot lab areas. The hot lab is kept locked at all times.....

c. Dose Calibrator ( ) N/A

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

(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 N/A

(6) Readings mathematically corrected if linearity error is greater than 10% per [35.50(d)] (~~✓~~Y ( ) N N/A

(7) Records maintained [35.50(e)] (~~✓~~Y ( ) N

(8) RSO signs linearity, accuracy and geometry dependence tests [35.50(e)] (~~✓~~Y (✓N

N/C

Remarks Linearity tests performed on 3-10-92 and on 6-8-92 were not signed by the RSO.....

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d. Survey instruments ( ) N/A

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

Remarks Item (4) could not be verified as there was two NMT available for interview. There was only one survey meter Victoreen 498.

e. Syringes containing RAM properly labeled and shielded unless contraindicated per [35.60] ( ) Y ( ) N NI

f. Vials containing RAM properly labeled and shielded per [35.61] ( ) Y ( ) N NI

Remarks See remark in item (d) above.

7. RADIOLOGICAL PROTECTION PROCEDURES

a. Radioactive material used in accordance with current procedures [L/C] (✓) Y ( ) N

Remarks

b. Individuals' understanding of current procedures is adequate

(1) in general rules for safe use of RAM ( ) Y ( ) N
(2) in emergency procedures ( ) Y ( ) N } NI

Remarks The training records indicated that the NMT was given annual refresher training by the consultant.

8. MATERIALS

a. Licensee uses unit doses (✓) Y ( ) N

b. Licensee uses generators ( ) Y (✓) N

c. Licensee possesses sealed sources or brachytherapy sources per [35.59] (✓) Y ( ) N

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

Remarks .....

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e. Molybdenum-99 breakthrough (✓) N/A

(1) Test performed per [35.204(b)] ( ) Y ( ) N
(2) Records maintained per [35.204(c)] ( ) Y ( ) N

Remarks .....

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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 of leak tests and inventories maintained for 5 years (✓) Y ( ) N

N/C Remarks Inventory records of 5-8-92, 7-16-92, 1-5-92, 1-26-93, 4-30-93 not signed by the RSO

Leak test records of 1-26-93 and 7-14-93 not signed by the RSO

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

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

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

Remarks Records were reviewed during the inspection and they appeared to be in order. No personnel interviews conducted as no N.M.T. was available.

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10. AREA SURVEYS ( ) N/A

a. Ambient exposure rate surveys conducted per [35.70(a),(b),(c)] (Y) Y ( ) N
b. Contamination surveys conducted per [35.70(e),(f)] (Y) Y ( ) N
c. Trigger levels established [35.70(d),(g)] (Y) Y ( ) N
d. Exposure rate survey records in mR/hr (Y) Y ( ) N
e. Contamination survey records in dpm/100 cm^2 (Y) Y ( ) N
f. Records maintained per [35.70(h)] (Y) Y ( ) N

Remarks .....

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11. RADIOPHARMACEUTICAL THERAPY ( ) N/A

a. Licensee provides safety instruction per [35.310] and implements safety precautions [35.315] or equivalent [L/C] ( ) Y ( ) N } NI
b. Patient room contamination surveys per [35.315] ( ) Y ( ) N }
c. Release of patients containing radiopharmaceuticals meets [35.75] (Y) Y ( ) N

d. Thyroid burden measured on individuals involved in dose administrations [35.315(a)(8)] ( ) Y ( ) N

e. Records maintained ( ) Y ( ) N

Remarks No thyroid burdens measurements required. I-131 used in capsule form and the dosages were less than 30 mCi (under 10 mCi).

12. BRACHYTHERAPY (✓) N/A

a. Licensee provides safety instruction [35.410] and implements safety precautions [35.415] or equivalent [L/C] ( ) Y ( ) N

b. Patient surveys performed per [35.406] ( ) Y ( ) N

c. Release of patients containing permanent implants meets [35.75] ( ) Y ( ) N

d. Release of patients treated with temporary implants meets [35.404] ( ) Y ( ) N

e. Brachytherapy sources inventoried per [35.406] ( ) 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 Monthly

b. Supplier is NVLAP - approved (✓) Y ( ) N

c. Reports reviewed by ~~RSO~~ Physicist Frequency ~~Q~~ Monthly.

d. NRC inspector reviewed personnel monitoring records for

period 11-91 to 10-92

e. NRC forms or equivalent

(1) NRC - 4	( ) Y ( ) N	Complete	( ) Y ( ) N
(2) NRC - 5	(✓) Y ( ) N	Complete	(✓) Y ( ) N

f. List maximum exposures (millirems):

(1) Whole Body 170 mrem; (2) Extremity 76 mrem

g. Licensee has implemented an ALARA program [35.20] (✓) Y ( ) N

Remarks One X-ray Tech had an exposure of 8480 mrem. The Licensee notified NRC. The Licensee determined that this tech was administered a 6.0 mCi dosage of I-131 and continued work with her film badge on. (This was not occupational exposure).

14. PERSONNEL RADIATION PROTECTION - INTERNAL ( ) N/A

a. Potential for exposure of individuals to airborne RAM exists (✓) Y ( ) N
b. Monitoring for airborne radioactivity conducted per 20.201(b) to meet [20.103, 35.90 and 35.205] ( ) Y ( ) N] NI
c. Records maintained [20.401, 35.205, and L/C] ( ) Y ( ) N]
d. Bioassay program implemented as described in correspondence with NRC ( ) Y ( ) N

Remarks .....

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e. Radioactive gases

(1) Clearance time and safety procedures are posted [35.205(d)] (✓) Y ( ) N
(2) Reusable collection systems checked monthly ( ) Y ( ) N NI
(3) Ventilation rates checked each six months for negative pressure [35.205(e)] ( ) Y (✓) N

N/C

Remarks Ventilation rate check was not performed since 6-27-91 but the licensee continued to administer Xe-133 as late as 2-28-92.

15. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. RAM in effluents to unrestricted areas ( ) Y ( ) N] NI
b. Release in accordance with regulatory limits [20.105(a)] ( ) Y ( ) N]

Remarks .....

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

Remarks All was decayed in Storage.

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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 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 .....

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16. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with [19.13] (reports to individuals)	(✓) Y ( ) N ( )N/A
b. Licensee in compliance with [20.204] (theft or loss)	( ) Y ( ) N (✓)N/A
c. Licensee in compliance with [20.403] (incidents)	(✓) Y ( ) N ( )N/A
d. Licensee in compliance with [20.405] (overexposures)	(✓) Y ( ) N ( )N/A

Remarks One X-ray Tech received 8480 mrem in a month but the licensee determined that the individual was given a 6.0 mCi dosage of I-131 for hyperthyroidism and continued to wear her film badge. The licensee determined that this was not an occupational exposure.

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17. MISADMINISTRATIONS

a. Misadministrations have occurred	( ) Y (✓) N
(1) Diagnostic	( ) Y (✓) N
(2) Therapeutic	( ) Y (✓) N
b. Licensee in compliance with reporting therapeutic misadministrations [35.33(a),(b)]	( ) Y ( ) N N/A

c. Licensee in compliance with reporting diagnostic misadministrations, if required [35.33(c)] (✓) Y ( ) N
d. Appropriate action taken to prevent recurrence ( ) Y ( ) N
e. Records maintained [35.33(d)] ( ) Y ( ) N

Remarks .....

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18. POSTING AND LABELING

a. Form NRC-3 "Notice to Workers" posted (✓) Y ( ) N
b. Other posting and labeling per [20.203] (✓) Y ( ) N

Remarks .....

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19. TRANSPORTATION (10 CFR 71.5(e) and 49 CFR 171.189)

a. Licensee makes shipments of RAM ( ) Y (✓) N
b. If so, describe shipment content and method:

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c. Licensee is aware of 10 CFR 61 requirements ( ) Y ( ) N (✓)N/A
d. Licensee classifies and characterizes waste ( ) Y ( ) N (✓)N/A
e. Shipments

(1) Authorized packages used [173.415,416] ( ) Y ( ) N (✓)N/A
(2) Package type used .....
(3) For DOT-7A packages, performance test record on file [173.415(a)] ( ) Y ( ) N (✓)N/A
(4) For special form sources, performance test record on file [173.476(a)] ( ) Y ( ) N (✓)N/A
(5) Packages properly labeled [172.403, 173.441] ( ) Y ( ) N (✓)N/A
(6) Packages properly marked [172.300] ( ) Y ( ) N (✓)N/A
(7) Proper shipping papers prepared and used [172.200-204] ( ) Y ( ) N (✓)N/A

Remarks .....

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f. Licensee makes return shipments of radiopharmacy doses ( ) Y ( ) N ( )N/A

(1) If YES, licensee assumes responsibility of all shipper requirements ( ) Y ( ) N NI

(2) If NO, describe arrangements made between licensee and radiopharmacy as to performance of shipper responsibilities:

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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)] ( ) Y ( ) N N/A

b. Records include all information outlined in [30.35(g)] ( ) Y ( ) N

Remarks .....

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21. INDEPENDENT MEASUREMENTS

a. Survey instrument used Ludlum H-C

b. NRC Serial No. 33508

c. Inspector's measurements were compared to licensee's ( ) Y (✓) N

d. Describe the type and results of measurements:

Hot Lab areas surveyed and no abnormal radiation levels noted.

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22. BULLETINS AND INFORMATION NOTICES

a. Bulletins, Information Notices, etc., received by the licensee ( ) Y ( ) N

b. Licensee took appropriate actions in response to Bulletins, INs, etc. ( ) Y ( ) N

Remarks The physicist Michael Teeters of Bio Med stated that he keeps track of such items and any other correspondence from the NRC.

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23. CONTINUATION OF REPORT ITEMS

24. LIST OF VIOLATIONS

A. 10 CFR 35.205(e) the licensee used radioactive xenon-133 gas in the nuclear medicine scanning room and did not measure the ventilation rates therein from June 27, 1991 to June 2, 1993.

B. 10CFR 35.50(e)(3) as of June 2, 1993, the licensee's record of the quarterly linearity test of its dose calibrator performed on March 10, 1992 and June 8, 1992 did not include the signature of the Radiation Safety Officer.

C. 10CFR 35.59(d) as of June 2, 1993, the licensee's records of leakage test results of January 26, 1993 and July 16, 1992 did not contain the signature of the Radiation Safety Officer.

D 10 CFR 35.59(g) as of June 2, 1993, the licensee's records of physical inventories of its sealed sources conducted on April 30, 1993, January 26, 1993, October 26, 1992, July 16, 1992 and May 8, 1992 did not contain the signature of the Radiation Safety Officer.

E. 10CFR 35.22(a)(3) on March 4, 1992, the licensee's Radiation Safety Committee met and conducted business and the Radiation Safety Officer was not present.

25. PERFORMANCE EVALUATION FACTORS

Licensee St. Mary's Hospital, Orange, NJ

Inspector Sattar Lodhi

Inspection Date 6-2-93

a. Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight ( ) Y (X) N

b. RSO too busy with other assignments ( ) Y (X) N

c. Insufficient staffing ( ) Y (X) N

d. Radiation Safety Committee fails to meet or functions inadequately ( ) Y (X) N

e. Inadequate consulting services or inadequate audits ( ) Y (X) N

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

The licensed activities were suspended in July 1992. There was no nuclear medicine tech on staff. The Licensee suspended these activities because of lack of patients. This is an ambulatory care facility. The current RSO is the also the only authorized user and practices at a sister Hospital in Newark, NJ.

Regional follow-up on above PEFs citations:

ADDENDUM

INTERIM FIELD NOTES

QUALITY MANAGEMENT (QM) PROGRAM

1. GENERAL

a. License number(s): 29-20597-01

b. Docket number(s): 030-19962

c. Last inspection date(s): 10-23-90

d. Current inspection date(s): 6-2-93

2. MODALITIES

a. Procedures the licensee performs:

(1) Teletherapy	Y	(N)
(2) Gamma Stereotactic Radiosurgery	Y	(N)
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y	(N)
(4) All Other Brachytherapy	Y	(N)
(5) NaI I-125 or I-131 > 30 microCi	(Y)	N
(6) Therapeutic Radiopharmaceutical Other than (5)	Y	(N)

3. PROGRAM

a. Licensee has a written QM program, as applicable, that covers all policies/procedures that require a written directive and program review [35.32(a) and (b)(1)] (Y) N (SW)

b. Written QM program and certification (for existing licensees) submitted to NRC [35.32(f)(2)] (Y) N
Date: 1-17-92

Remarks .....

4. SUPERVISION

a. Supervised individual(s) instructed in the QM program applicable to the modality of use [35.25(a)(1)] Y N (SW) NI

(1) If any individual(s) has not received training, document their names and position. Additionally, briefly describe the reasons as stated by the individual, the RSO, and the supervising authorized user:

The dep. NM activities are suspended and there is no NMT or staff currently

Date: .....

Remarks .....