APPENDIX B

NUCLEAR MEDICINE INSPECTION FIELD NOTES*

Region I

Inspection Report No. 93-001 License No. 08-01738-02, 03

Licensee (Name and Address): Docket No. 030-01317 / 030-06895

Department of the Army
Walter Reed Med. Ctr.

Washington, DC

Licensee Contact: Col. Arthur G. Samiljan Telephone No. 301-427-5104

Last Amendment No. Date of Amendment

Priority: 1

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 8/11-14 1992

Date of This Inspection 7/20 - 8/4/93

Type of Inspection:
( ) Announced
( ) Routine
( ) Initial
(✓) Unannounced
( ) Special
( ) Reinspection

Next Inspection Date 08/94 (✓) 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: Teresa Hall Dorden (Signature) Date: 7/31/93

Approved: [signature] (Signature) Date: 8/1/93

2/66

*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:

Represented RSO's from WRAIR (
WRAMC
AFIP

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

Remarks:

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: Meetings:
9/21/92
12/13/92
3/8/93
6/12/93

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:

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: .....

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: .....

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

a. Last inspection conducted on 8/11-14/92

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

c. Response letter or 591 dated 12/1/92

d. Violations from Previous Inspection:

Requirement	Violation	Corrective Action Taken (Y/N)	Status
10 CFR 20.201/20.105	Failure to verify levels in unrestricted hallway	Yes	C
35.315(a)(8)	Failure to measure thyroid burden	Yes	C

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

Explain: All Records for bioassays were not immediately available at time of inspection. 8/4/93 telephone conversation between RSO & inspector revealed that the person thought to have been present at time of I^{131} administration and/or cleanup was coordinator of cleanup project and was not actively involved in actual I^{131} activity.

3. SCOPE OF PROGRAM

a. Licensee has multiple authorized locations of use ( ) Y ( ) N

b. If so, list location(s) inspected ( ) N/A

WRAMC - Georgia Ave, DC → Med + Research

Keys - Rockville } Research

EMat - Rockville

c. List those individuals contacted during inspection:

Watkins, Nuc. Pharmacist Col/mc Francis O'Donnell, Dept for Prev Mdl Services

Lt. Col. Arthur Samilian, RSO Dr. Yvonne M. Andejeski, Maj. Rad. Oncol

Yvette Sayer, NMT Sgt. Green

Sgt. Tina Dunts, Student

Pat Ferguson, RIA

*Indicates presence at exit meeting

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

NM = 35,100, 35,200, 35300, Accelerator → In 111

Research - Usuals - H^3, C^{14}, Cr, S_{35}

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:

4. INTERNAL AUDITS OR INSPECTIONS

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

(1) Audits conducted by Consultant RSO, H.P.

(2) Frequency Annually

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

c. Records maintained (✓) 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 (✓) Y ( ) N

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

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

(4) Records maintained (✓) 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 One facility is presently being decommissioned (Buckman Bld.). Premature license amendment was submitted to R.I. to release bldg. Inspector explained that the results of the decon must be submitted to NRC for evaluation prior to release of bldg. & the NRC must actually grant the release for unrestricted use

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 Concern: Taft Research facility - Attempt is made to secure the front of the bldg. However, back entry (from office side) immediately adjacent to the front closed door can be entered unhindered & unchallenged. Inspector was accompanied by RSO and spoke to Dept. Head about potential problem. RSO & Mgmt agreed to remove the

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
(6) Readings mathematically corrected if linearity error is greater than 10% per [35.50(d)] (✓) Y ( ) N
(7) Records maintained [35.50(e)] (✓) Y ( ) N
(8) RSO signs linearity, accuracy and geometry dependence tests [35.50(e)] (✓) Y ( ) N

Remarks

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

Remarks .....

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

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

Remarks ~~A problem~~ .....

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

Remarks .....

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

Remarks .....

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9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

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

Nuc. Med. - Receives own
Health Physics receives Researcher's materials

b. Opening procedures established and followed per [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 Transfers are to licensee's authorized users - Uses dedicated vehicle

10. AREA SURVEYS ( ) N/A

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

Remarks

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
b. Patient room contamination surveys per [35.315] (✓) Y ( ) N
c. Release of patients containing radiopharmaceuticals meets [35.75] (✓) Y ( ) N

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

e. Records maintained (✓) Y ( ) N

Remarks Thyroid burdens are measured on all persons assisting with administrations & clean up of rooms. Most records located for all involved except one individual who has moved on to another military base. RSO promised to contact individual & get back to inspector. L/C exception for dedicated room to remain locked ~~until~~ for decay until clean up prior to ~~[illegible]~~ next patient treatment

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 Army Ionizing Radiation Dosimetry Center Frequency monthly

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

c. Reports reviewed by RSO Frequency Quarterly

d. NRC inspector reviewed personnel monitoring records for

period June 1992 to May 1993

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 ≤ Alara 2 limits (2) Extremity ≤ ALARA 2 limits

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

Remarks .....

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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
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
(3) Ventilation rates checked each six months for negative pressure [35.205(e)] ( ) Y ( ) N

Remarks .....

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15. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. RAM in effluents to unrestricted areas ( ) Y ( ) N

b. Release in accordance with regulatory limits [20.105(a)] (✓) Y ( ) N

Remarks Some Drain Disposal
Hoods are monitored & filters are cleaned

c. Describe waste disposal method(s)- solid and liquid: Use Quadrex & Chem Nuclear

Remarks 5/26/93 7 Drums
2/24/93 5 "
12/2/92 49 "
8/12/92 9 + 20
Presently waste that is generated in Md can be shipped to SC (Barnwell but waste generated in SC is held in storage

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 Waste collected from SC facility is stored or decayed in storage. Waste collected from Maryland facilities is still sent to North Carolina

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 .....

17. MISADMINISTRATIONS

See Comments

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 NA

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

another pt.

Remarks - Bone scan pt. was injected with Indium 111 platlet while this was not an NRC defined misadministration the QC for pt. ID and dose management was examined. The licensee initiated corrective action in this Identification process which is applicable to all dose administrations

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:
Licensee has designated placarded vehicle

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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

(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~~

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

Remarks .....

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21. INDEPENDENT MEASUREMENTS

NI

a. Survey instrument used .....

b. NRC Serial No. .....

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

d. Describe the type and results of measurements:

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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 .....

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23. CONTINUATION OF REPORT ITEMS

24. LIST OF VIOLATIONS

25. PERFORMANCE EVALUATION FACTORS

Licensee WRAMC ..... Inspector T. H. Dunden

..... Inspection Date 7/20-23/93

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

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

c. Insufficient staffing ( ) Y (✓) N

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

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

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

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Regional follow-up on above PEFs citations:

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ADDENDUM

INTERIM FIELD NOTES

QUALITY MANAGEMENT (QM) PROGRAM

1. GENERAL

a. License number(s): 08-01738-02

b. Docket number(s): 030-01317

c. Last inspection date(s): 08/92

d. Current inspection date(s): 07-20 to 09-23-93

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: 1/92

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)

(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:

None were identified

Date: .....

Remarks .....

Exit
Good Oversight
H/C from Last
open Bioassay

Serious Concerns:
1. Misadministration
2. Security - Taft

Col. Jason Zaytchuk, acting, Commander