

APPENDIX B

NUCLEAR MEDICINE INSPECTION FIELD NOTES*
Region 1Inspection Report No. 91-001License No. 20-00742-18

Licensee (name and address)

Docket No. 20-09062BETH ISRAEL HOSPITAL
330 BRUDLINE AVE.
ROSTON MA 02615Licensee Contact ROSEMARY KENNEDY RSWTelephone No. 617-725-0510Last Amendment No. 15Date of Amendment 9-3-91Priority: 61

Program Codes:

- | | |
|---|---|
| <input checked="" type="checkbox"/> 02110 - Broad Scope | <input type="checkbox"/> 02120 - Limited |
| <input type="checkbox"/> 02121 - Custom | <input type="checkbox"/> 02200 - Private Practice - Limited |
| <input type="checkbox"/> 02209 - In Vivo | <input type="checkbox"/> 02201 - Private Practice - Custom |
| <input type="checkbox"/> 02210 - Eye Applicator | <input type="checkbox"/> 02220 - Nuclear Medical Van |
| <input type="checkbox"/> 02400 - Veterinary | <input type="checkbox"/> 02410 - In Vitro |
| <input type="checkbox"/> 2500 - Pharmacy | <input type="checkbox"/> Other - |

Date of Last Inspection 7-30+31-90Date of This Inspection 9-3-91 to 9-4-91

Type of Inspection:

- ☐
- Announced
-
- ☒
- Routine
-
- ☐
- Initial

- ☒
- Unannounced
-
- ☐
- Special
-
- ☒
- Reinspection

Next Inspection Date. 9-92 ☒ 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: Steven L. Bartman
(Signature)Date 9/11/91William Davidson 9-11-91Approved: M. S. Stuckey
(Signature)Date 9/26/91

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

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 7-31-90
- b. Violations or deviations were identified ☐ Y ☒ N
- c. Response letter or 591 dated 7-31-90
- d. Violations from Previous Inspection

<u>Requirement</u>	<u>Violation</u>	<u>Corrective Action Taken (Y/N)</u>	<u>Status</u>

4. INTERNAL AUDITS OR INSPECTIONS

- a. Audits or inspections are conducted (✓) Y () N () N/A
- (1) Audits conducted by HARVARD / HP STAFF
- (2) Frequency MONTHLY 1-2 TIMES / YEAR
- b. Audits are required by license condition (✓) Y () N
- c. Records maintained (✓) Y () N

Remarks.

• HARVARD MONITORS BI IMMEDIATELY IF CONTAMINATION
 $> 1000 \text{ dpm} / 100 \text{ cm}^2$

- $> 100 \text{ dpm} / 100 \text{ cm}^2$ the lab appears on report

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. ANY USER OF RAM MUST TAKE THE HARVARD

TRAINING COURSE BEFORE USING RAM

- SEVERAL TRAINING VIDEOS ARE AVAILABLE ON
 VARIOUS RAD SAFETY PROCEDURES AND TOPICS

- REFRESHER TRAINING OFFERED WEEKLY

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

Remarks.

d. Survey instruments

- | | |
|--|---|
| (1) Appropriate operable survey instruments possessed per [35.120,220,320,420] or available per [35.520] | (<input checked="" type="checkbox"/> Y () N () N/A |
| (2) Calibration performed as required in [35.51] | (<input checked="" type="checkbox"/> X () N |
| (3) Records maintained [35.51(d)] | (<input checked="" type="checkbox"/> Y () N |
| (4) Proper operation checked with check source per [35.51(c)] | (<input checked="" type="checkbox"/> Y () N |

Remarks.

- EXAMINE METERS SENT TO NUCLEAR INSTRUMENTS
- CONTAMINATION METERS TESTED BY HAWAII
I A-226 OR A PULSER

- 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.

7. RADIOLOGICAL PROTECTION PROCEDURES

- a. Radioactive materials used in accordance with current procedures [L/C] (☒ Y () N

Remarks.

f. Leak tests and Inventory

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

Remarks.

OLD PART
35

INVENTORY DONE ANNUALLY MR L/C

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

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

- PACKAGES ARE ROUTINELY TAKEN FROM RECEIVING DIRECTOR TO LABS - LABS ARE RESPONSIBLE FOR SURVEYING.

NOTICE BEFORE HANDS, PACKAGES ARE TAKEN TO HOT LABS BY CARRIER WHO IS ESCORTED BY SECURITY hot lab is secured by security afterwards

- | | |
|---|---|
| b. Opening procedures established and followed [20.205(d)] | (<input checked="" type="checkbox"/>) Y () N |
| c. Incoming packages wiped per [20.205(b)] | (<input checked="" type="checkbox"/>) Y () N |
| d. Incoming packages surveyed per [20.205(c)] | (<input checked="" type="checkbox"/>) 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] | (<input checked="" type="checkbox"/>) Y () N |

Remarks.

- e. Brachytherapy sources inventoried per [35.40] ☐ 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.

OLD PART 35. ~~PHYSICISTS~~ PHYSICISTS FROM THE JOINT COMMISSION PARTICIPATE IN THE RECORDS INVENTORY ANNUALLY AND ONLY ONE AREA IN STORAGE ROOM SURVEYED. This is in accordance with the current license conditions.

13. PERSONNEL RADIATION PROTECTION - EXTERNAL

- a. Film or TLD supplier LANDOLPH Frequency ANNUALLY
 b. Supplier is NVLAP - approved ☒ Y ☐ N
 c. Reports reviewed by _____ Frequency ANNUALLY
 d. NRC inspector reviewed personnel monitoring records for period 5-90 to 8-91
 e. NRC forms or equivalent
 (1) NRC-4: ☐ Y ☒ N Complete: ☐ Y ☐ N ☒ N/A
 (2) NRC-5: ☒ Y ☐ N Complete: ☒ Y ☐ N ☐ N/A
 [20.401(a)]
 f. List maximum exposures (millirem): All within ALARA when using requested material.
 g. Licensee has implemented an ALARA program [35.20] ☒ Y ☐ N

Remarks.

³²P user's badge.
 #30 millirem recorded on a ³²P user's badge. User was on vacation during the period covered by the badge and placed it in close proximity to an experiment (⁷⁶P gel was placed in same drawer.)

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

16. NOTIFICATION AND REPORTS

- | | |
|--|----------------------|
| a. Licensee in compliance with [19.13]
(reports to individuals) | () Y () N (✓) N/A |
| b. Licensee in compliance with [20.402]
(theft or loss) | () Y () N (✓) None |
| c. Licensee in compliance with [20.403]
(incidents) | () Y () N () None |
| d. Licensee in compliance with [20.405]
(overexposures) | () Y () N (✓) None |

Remarks.

17. MISADMINISTRATIONS

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

Remarks.

Non-reportable misadministration on 11/30/90
 Error of "In DTPA administered instead of "In CE
 Brigham and Women's sent "In ^{DTPA} which was correctly issued
 to Beth Israel but due to the workload the tech did not
 read all of the label and administered the pharmaceutical.
 Whole body dose 0.015 Rad, Bladder (target organ) 0.85 Rad
 Technicians informed to always read the entire label before
 administering the dose to a patient. B&W informed of incident

f. Licensee make 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:

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.

21. INDEPENDENT MEASUREMENTS

a. Survey instrument used Ludlum 3 End Window GM

b. NRC Serial No. 7765

c. Last date of calibration August 1, 1991

d. Inspector's measurements were compared to licensee's

☒ Y ☐ N

e. Describe the type and results of measurements:

*Surveys of Labs, of RHM storage areas, New Mex Dept
ALL within regulatory limits.*

25. PERFORMANCE EVALUATION FACTORS

Licensee
(name &
location)

BETH ISRAEL HOSP
330 BROOKLINE AVE
BOSTON, MA 02215

Inspector

DAVIDSON

COMPTON/ANCAE

Inspection Date

9-3-94-S

- 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):

Regional follow-up on above PEFs citations: