

APPENDIX B

NUCLEAR MEDICINE INSPECTION FIELD NOTES^{*} Region II

Inspection Report No. 9-001 License No. 20-19761-02
Licensee (name and address) Dana-Farber Cancer Institute Docket No. 030-20020
111 Binney Street
Boston Massachusetts 02115
Licensee Contact Steven Alfari RSO Telephone No. 617-732-3487
Last Amendment No. 03 Date of Amendment 11-28-90
05 11-5-97
Priority :
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"/> 02500 - Pharmacy | <input checked="" type="checkbox"/> Other - 3510 |

Date of Last Inspection August 16, 1990 for Docket 030-20020
June 21-22, 1989 for Docket 030-19201

Date of This Inspection October 24, 1991

Type of Inspection: ☐ Announced ☒ Unannounced
☒ Routine ☐ Special
☐ Initial ☐ Reinspection
0-94 for Docket 030-19201

Next Inspection Date. 0-94 for Docket 030-19201 ☒ Normal ☐ Reduced ☐ Extended
Docket 030-20020

Summary of Findings and Action:

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

Inspector: Fanny M. [Signature] Date 11-8-91
(Signature)

Approved: _____ Date _____
(Signature)

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

9301080252 920520
PDR FOIA
STOLL 92-58 PDR

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.

Physicians still come over from Brigham and Women's but the work under the supervision of Dr. Kaplan. Dana-Farber has hired a new physician, so soon B+W physicians will not be required at Dana.

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 8-16-90
- b. Violations or deviations were identified (✓) Y () N
- c. Response letter or 591 dated 10-3-90
- d. Violations from Previous Inspection

Requirement	Violation	Corrective Action Taken (Y/N)	Status
L.C. 25 (Item 7)	No Annual Review of the Radiation Safety Program	Y	Closed

4. INTERNAL AUDITS OR INSPECTIONS

- a. Audits or inspections are conducted ☒ Y () N () N/A
- (1) Audits conducted by Medical Physicist / RSO
- (2) Frequency Quarterly / annually
- b. Audits are required by license condition ☒ Y () N
- c. Records maintained ☒ Y () N

Remarks.

Medical Physicist, Bob Zimmerman, audits N.M. program quarterly.
 individual on probation for unsafe Bi-212 generator use.

5. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

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

Remarks.

Meeting w/ maintenance twice/year for RS training. Maintenance personnel supervised if working in RRM areas.
 Security provided phone #s of RSO if a problem after-hours is found.
 Dave Forshaw (ex. housekeeper - training all housekeeping personnel (also in Spanish) on radiation signs and symbols.
 Housekeeping not allowed in hot lab or injection room.

- 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.

Two meetings held every year (in Feb. and March) for retraining of staff.
 Initial training sessions held every week by RSO.

- 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"/> Y () 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.

N.M. counts wipes w/ Ludlum 177 GM w/ NaI probe. Probe is placed in leaded cave to decrease Background to ~ 50 cpm. Efficiency = 2.8%.

- | | |
|---|---|
| e. Syringes containing RAM properly labeled and shielded unless contraindicated per [35.60] | (<input checked="" type="checkbox"/> Y () N |
| f. Vials containing RAM properly labeled and shielded per [35.61] | (<input checked="" type="checkbox"/> Y () N |

Remarks.

7. RADIOLOGICAL PROTECTION PROCEDURES

- | | |
|---|---|
| a. Radioactive materials used in accordance with current procedures [L/C] | (<input checked="" type="checkbox"/> Y () N |
|---|---|

Remarks.

Last review of procedures in N.M. 9-6-90 by RSO, Dr. Kaplan + CUMT

6-11-91 : RSO sent memo to permit holders on the wearing of lab coats, gloves, and closed toed shoes when handling RAM.

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)] | (<input checked="" type="checkbox"/>) Y () 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.

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

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

All N.M. deliveries and research deliveries made during working hours. Courier from B+W delivers package to NM hold'g. Receiving Area for research packages is DANA 2. No off-hours deliveries. Investigator is contacted and comes to pick up package. All packages transported via enclosed walkways, bridges, or underground tunnels.

- | | |
|---|---|
| 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] N/A | () Y () N |
| f. Records of surveys and receipt/transfer maintained per [20.401(b) and 30.51] | (<input checked="" type="checkbox"/>) Y () N |

Remarks.

Paul Salisbury - receiving personnel - has been trained by RSO to perform wipes and surveys.

- e. Brachytherapy sources inventoried per [35.406] () Y () N
 f. Brachytherapy source storage area surveyed quarterly and records signed by RSO [35.59(h)] () Y () N
 g. Records maintained () Y () N

Remarks.

All therapy performed at B+W.

13. PERSONNEL RADIATION PROTECTION - EXTERNAL

- a. Film or TLD supplier Lordauer Frequency month
 b. Supplier is NVLAP - approved () Y () N
 c. Reports reviewed by Harvard / RSO Frequency month
 d. NRC inspector reviewed personnel monitoring records for period 7-90 to 8-91
 e. NRC forms or equivalent
 (1) NRC-4: () Y () N Complete: () Y () N () N/A
 (2) NRC-5: () Y () N Compleats: () Y () N () N/A
 [20.401(a)]

f. List maximum exposures (millirem): minimal exposures

- g. Licensee has implemented an ALARA program
 [35.20] Harvard calls if badge reading > 100 mrem whole body, quarter or > 400 mrem extremity / quarter. () Y () N

Remarks.

N/C Uass. College of Pharmacy Students not badged here, but badged by college. Students don't inject and can't dispense.
Physicians acting as visiting authorized users ~~badged~~ from B+W badged at B+W. Physicians do not handle RAM and primarily read scans.

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 [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 (<input checked="" type="checkbox"/>) N/A |
| b. Licensee in compliance with [20.402]
(theft or loss) | () Y () N (<input checked="" type="checkbox"/>) None |
| c. Licensee in compliance with [20.403]
(incidents) | (<input checked="" type="checkbox"/>) Y () N () None |
| d. Licensee in compliance with [20.405]
(overexposures) | () Y () N (<input checked="" type="checkbox"/>) None |

Remarks.

- 1) Spill in U.M. W/ ~ 5mCi Tc-99m in scan room.
Area covered and counted next morning. Counts < Bkgd.
- 2) 6-20-91: S-35 spill reading 0.2mR/hr. Cleaned, resurveyed
6-21-91. Down to Bkgd.
- 3) 11-5-90: Hot shoes (I-125) kept for decay. Area of contamination
not found. Licensee checked all applicable areas.
- 4) 11-28-90: H-3 spill. Cleaned down to 500cpm/100cm². No personnel contaminated.
- 5) 4-19-91: P-32 spill of 100 uCi. Pressure buildup caused tube to explode.
Individual contaminated on arms and scrubbed. Clothing contaminated and held.
Covered hot areas w/ Lucite. Lucite removed 7-15-91. Dose to contaminated
individual was 90 mrem. Film badge results were minimal.
Now limit boiling time so pressure buildup does not occur.

17. MISADMINISTRATIONS

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

Remarks.

8-29-90 25.4 mCi Pertech instead of 25mCi MDP
Techs re-educated and vials color coded.

5-7-12-91 Pertech instead of MDP

7-23-91 25.7 mCi Pertech instead of 25mCi MDP

→ Techs re-educated. Also placed vials in separate identification
locations behind shielding. Tech in the morning also indicated
that she was often rushed in the morning due to having to
pick up the doses at BtW, so changed procedure to having
doses delivered to Nuclear Medicine.

- f. Licensee makes return shipments of radiopharmacy doses

☐ 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:

☐ Y ☐ N

Hold Bulk Tc-99m for OIS.
Return empty cases to B+W

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.

All incidents, "areas of use", and spill records are kept in a log.

21. INDEPENDENT MEASUREMENTS

- a. Survey instrument used Ludlum 16
b. NRC Serial No. 81531
c. Last date of calibration Apr 27, 91
d. Inspector's measurements were compared to licensee's
e. Describe the type and results of measurements:

☒ Y ☐ N

Reviewed several labs just surveyed by Ed Conlon of the Larvae Group on his monthly survey. Results comparable.

25. PERFORMANCE EVALUATION FACTORS

Licensee
(name &
location)

Dana Farber Cancer Institute
44 Brimley Street
Boston, MA 02115

Inspector

Penny Nessen

Inspection Date

10-24-91

- 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:

Continue on normal inspection frequency.

11/15/91

PAGE 1

U.S. NUCLEAR REGULATORY COMMISSION
REGION 1
OPEN ITEMS TRACKING SYSTEM

DOCKET NUMBER: 30-19201

REPORT NUMBER	STATUS	DATE OPEN	DATE CLOSED	REVIEWER NAME	OPTION	CLOSING REFER
1 91-001	CLOSED	10/24/91	10/24/91	NESSCH	VIOL	91-001
ITEM: CLEAR INSPECTION THIS LICENSE.						

D/63