

APPENDIX B

NUCLEAR MEDICINE INSPECTION FIELD NOTES*

Region I

Inspection Report No. 020-01808/92-0

License No. 20-00289-07

Licensee (name and address)

Docket No. 020-01808

NEHD
180 Kilgus Road
Amherst, Massachusetts

Licensee Contact Shelley Cobb

Telephone No. 617-432-8509

Last Amendment No. 30

Date of Amendment May 22, 1991

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 type="checkbox"/> Other - |

Date of Last Inspection 24-30 Jan 1991

Date of This Inspection 13-14 Jan 1992

Type of Inspection: ☐ Announced ☒ Unannounced
☒ Routine ☐ Special
☐ Initial ☒ Reinspection

Next Inspection Date. 1/93 ☐ 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 R. Constantine
(Signature)

Date 1/22/92

9301120332 920520
PDR FOIA
STOLL 92-58 PDR

Approved: M. Shubert
(Signature)

Date 2/19/92

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

4. INTERNAL AUDITS OR INSPECTIONS

- a. Audits or inspections are conducted ☒ Y ☐ N ☐ N/A
- (1) Audits conducted by Production Safety Office
- (2) Frequency Varies according to use
- b. Audits are required by license condition ☐ Y ☒ N
- c. Records maintained ☒ Y ☐ N

Remarks.

*Frequency of inspections delineated on
back-up material.*

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.

*merely acceptable not mentioned on
back-up material as a requirement.*

- c. Supervision of individuals by authorized user
in accordance with [35.25] ☒ Y ☐ N

Remarks.

f. Leak tests and Inventory

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

Remarks.

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

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

Packages are brought to the Fire Med Dept by carrier escorted by security. Packages left in Hot Lab which is reserved. Rad Safety Office receives all other packages.

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

Remarks.

16. NOTIFICATION AND REPORTS

- | | |
|--|--|
| a. Licensee in compliance with [19.13] (reports to individuals) | <input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> N/A |
| b. Licensee in compliance with [20.402] (theft or loss) | <input type="checkbox"/> Y <input type="checkbox"/> N <input checked="" type="checkbox"/> None |
| c. Licensee in compliance with [20.403] (incidents) | <input type="checkbox"/> Y <input type="checkbox"/> N <input checked="" type="checkbox"/> None |
| d. Licensee in compliance with [20.405] (overexposures) | <input type="checkbox"/> Y <input type="checkbox"/> N <input checked="" type="checkbox"/> None |

Remarks.

17. MISADMINISTRATIONS

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

Remarks.

f. Licensee takes return shipments of radiopharmacy doses

(X) Y () N () N/A

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

(X) Y () N

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

~~not~~ N/A Licensee did not survey Limited Quantity shipment to ensure that criteria were met. (i.e. 0.5 mCi at surface)

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)]

(X) Y () N

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

(X) Y () N

Remarks.

21. INDEPENDENT MEASUREMENTS

a. Survey instrument used Lothalium 14C End Window GdM

b. NRC Serial No. 9657

c. Last date of calibration 11/91

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

(X) Y () N

e. Describe the type and results of measurements:

All within regulatory limits

25. PERFORMANCE EVALUATION FACTORS

Licensee New England Deaconess Hospital
(name & 1000 Beacon St., Boston, MA 02115
location) 1000 Beacon St.

Inspector Charles Amato
Steven Courtemanche
Inspection Date 1/13-14/92

- 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):

Regional follow-up on above PEFs citations: