

MEDICAL

LICENSE FILE NO: _____

ATTACHED

DOCKET No. (s) 030-20020
030-19201

☒ Appendix A ☒ Appendix B ☒ Appendix C

INSPECTION REPORT NO. 89-001
Name: Dana-Farber Cancer Inst.
Address: 44 Binney Street
Boston, Massachusetts 02115

LICENSEE CONTACT: Dr. Treves, Chair, RSC
TELEPHONE NO.: (617) 732-3487

LICENSE NO: 20-19761-02 PRIORITY: 1 Program Code: 2110
20-19761-01 PRIORITY: 3 Program Code: 3510
PRIORITY: _____ Program Code: _____

INSPECTION DATE (s): June 21-22, 1989 TYPE OF INSPECTION: ☐ SPECIAL ☐ ANNOUNCED
CLERK 35 - April 11/17/84 ☒ ROUTINE ☒ UNANNOUNCED
Last Insp: 5/29/87 ☒ DAYSHIFT ☐ OTHER

SUMMARY OF FINDINGS AND ACTION

☐ NO NONCOMPLIANCE, CLEAR 591 ISSUED ☒ ACTION ON PREVIOUS NONCOMPLIANCE, APPENDIX B
☐ NO NONCOMPLIANCE, LETTER ☐ NONCOMPLIANCE, 591 ISSUED
☒ NONCOMPLIANCE, APPENDIX A ☒ SUPPLEMENTAL INFO, APPENDIX C

RECOMMENDATIONS
SEE APPENDIX C

☐ CHANGE PROGRAM CODE ☐ CHANGE PRIORITY TO: _____

☐ NEXT INSPECTION DATE: 6/92

PERSONS CONTACTED

* B. Janicki, PhD, Director for Research * F. Keech, CNMT
* B. Corbett, Assoc " " "
* S. Treves, MD, Chair, RSC
* B. Kaplan, MD, Dir Nuc Med, OFCI
* R. Ameling, RSO
S. Smeltzer, NMT

9301080184 920520
PDR FOIA
STOLL 92-58 PDR

* At ext
INSPECTOR: A. Lindwood
APPROVED: Jan A. Guschke for

J. Miller 8/21/89

REGION 1 Form 198-C
(June '88) 9301080184 JMM Shabady 8/24/89
APP

D/57

1. ORGANIZATION

- a. Organizational structure meets license requirements. (
- ☒
- Yes () No

[L/C]

Remarks. RSO splits time bet. OFCI & CH-8
HOC authorized users, 250 labs, 49 PIJohn Nigh, Administrative Assistant
Jerry Gellman, Supervisor of Radiology
Francis Hackett, CHMT

Dr. B. Jawicki, Dir. of Research

W. Corbett, Dir. of Res.

Kum. Am. 250

- b. Use supervised by authorized individuals. (
- ☒
- Yes () No [35.22(b)(2)])

Remarks.

W. Kaplan, M.D.

E. Krum, M.D. (2 days/week)

- c. Radiation Safety Committee meets at quarterly intervals.

(☒ Yes () No

- (1) Membership in accordance with 35.22(a)(1)] (
- ☒
- Yes () No

Remarks.

- (2) Record of Committee meetings. (
- ☒
- Yes () No [35.22(a)(4)])

Remarks.

- (3) Consultants. (
- ☒
- Yes () No

Remarks.

Harvard (HUTTS)

- e. Licensee uses the services of a visiting authorized user. NI

() Yes () No [35.27(a)]

- (1) Licensee has a copy of visiting authorized user license.

() Yes () No [35.27(a)(2)]

- (2) License has records (maintained for 2 years) of visiting authorized users last visit. () Yes () No [35.37(c)]

- f. License utilizes mobile nuclear medicine services.

() Yes () No [35.29]

- g. Licensee delegates RSO sufficient authority, organizational freedom, and management prerogative. (
- ☒
- Yes () No

- h. Appropriate review by Committee in accordance with 35.22(b). NI

() Yes () No

3. 2021

Briefly list medical procedures and their frequency.

For note from note - 12/15/1919
 The note is 12/15/1919
 For note from note - 12/15/1919
 The note is 12/15/1919

c. Records maintained. () Yes () No [06,016] (2) (X)

INSTRUCTION TO 100

training program.

(2) Retraining program implemented. (☒) Yes (☐) No
Remarks.

- large staff → a lot of time
- case planning team

Remarks:

10. Describe the QA program to mitigate therapeutic misadministrations.

(1) Have secondary checks of the dose calculations been done?

☐ Yes ☐ No

(2) Do the second party checks of the dose calculations provide assurance that the final treatment plan will provide the dose prescribed to the patient? ☐ Yes ☐ No

When the consultant is not available, the results for the patient are not available.

11. Have there been previous therapeutic misadministrations?

(1) If so, were they properly reported? ☐ Yes ☐ No

(2) Was proper medical care given for the patient pursuant to the RC medical consultant recommendations? ☐ Yes ☐ No

(3) Were appropriate actions implemented to prevent recurrence? ☐ Yes ☐ No

(4) Were the technologist and dosimetrist made aware of these actions? ☐ Yes ☐ No

(5) Do the licensee's QA/QC procedures address these actions to prevent recurrence? ☐ Yes ☐ No

3. RADIOLOGICAL PROTECTION PROCEDURES

a. Radiation Safety program changes reviewed. (Exception to changes without license amendment may be found in 35.13 and 35.606.)
☐ Yes ☐ No

Inspect when QA rule becomes final.

Report 19.

- c. Radioactive materials used in accordance with current procedures.
(☒) Yes () No [35.21(b)(2)]
Remarks.

(1) Describe individual's understanding of current procedures.

(2) Describe if any procedures

- a. accepted and accepted
- b. standard rules for safe use of
- c. procedures
- d. procedures
- e. are not in violation of
- f. instructions for use of
- g. emergency procedures posted.
- h. do licensee personnel understand emergency procedures.
- i. safety procedures for patient therapy in accordance with 35.315 and 35.415

7. MATERIALS, FACILITIES AND INSTRUMENTS

- a. Facilities as described in license application. () Yes () No
Remarks.

Volume, weight, quantity and use is indicated.
as
Remarks.

- c. Syringes containing radioactive material properly labeled and shielded unless contraindicated. (☒) Yes () No [35.60(a)(b)(c)]
- d. Vials containing radioactive material properly labeled and shielded.
(☒) Yes () No [35.61(a)(b)]

206 VI

1. Adherence to regulations. None

- (1) Adherence to breakthrough. ☐ Yes ☐ No [35.204(b)]
(2) Performed as required. ☐ Yes ☐ No [35.204(a)]
(3) Records maintained. ☐ Yes ☐ No [35.204(c)]
Remarks.

(4) Leak tests. ☒ Yes ☐ No

(5) Leak tests performed as required. ☒ Yes ☐ No [35.59(b)]
Dates and Remarks.

2. Control of sources.

(1) Control of Group VI sources. ☐ Yes ☐ No [35.59(g)] N/A

(2) Control of calibration sources. ☒ Yes ☐ No [35.59(g)]
Remarks.

3. Storage and use of radioactive materials.

(1) Method used to prevent an unauthorized individual locked

(2) Radioactive material secured to prevent unauthorized removal from an unrestricted area. ☒ Yes ☐ No [20.207]

Remarks.

(3) Area wide tested? ☒ Yes ☐ No
Remarks.

h. Instrumentation.

- (1) Operable survey instruments are as described or equivalent to those described in license application. ☒ Yes ☐ No
[35.120, 220, 320, 420]
Remarks.

Availability of radiation survey instruments is adequate for program.
☒ Yes ☐ No
 Remarks.

- (3) Calibration of survey instruments required. ☒ Yes ☐ No
 (a) Performed as required. ☒ Yes ☐ No [35.50]
 Dates and Remarks.

- (4) Records of calibration maintained for 2 years. [35.50(e)]
☒ Yes ☐ No

B. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

Receipt of incoming packages during "off-duty" hours by whom?

- (a) Where stored? Security? [L/C] Not in Lab
 (b) Survey of incoming packages. ☒ Yes ☐ No [20.205(b)(1)]
 Remarks.

- (1) Record of survey. ☒ Yes ☐ No [20.401(b)]
 Remarks.

- (c) Procedure for opening packages. ☒ Yes ☐ No [20.205(d)]
 Remarks.

- (d) Returned licensed material transferred in accordance with 10 CFR 30.41.
☒ Yes ☐ No
 Remarks.

2. (cont'd)


a. Records of receipt and transfer maintained. ☒ Yes ☐ No

[30.51]

Remarks.

9. PERSONNEL RADIATION PROTECTION - EXTERNAL

(Obtain information regarding whole body and extremity monitors)


a. Film or TLD badge supplier Lundgren Frequency Monthly/Quarterlyb. Reports reviewed by RSO? ☒ Yes ☐ No Others RSC?Frequency monthly(Are badges assigned to personnel as per licensee's correspondence with NRC?) c. NRC inspector reviewed personnel monitoring records for period 10/87
to 3/89
One personnel deny indications on film badge.

d. NRC forms or equivalent.

(1) NRC-4: ☐ Yes ☒ No Complete: ☐ Yes ☐ No
Necessary ☐ Yes ☒ No(2) NRC-8: ☒ Yes ☐ No Complete: ☒ Yes ☐ No

[20.401(a)]

Remarks

*One personnel in Meyer, room 249 was working with 2nd
generator of I-131 without film badge. Failure of
Permit Holder to notify RSO of new worker.* e. Maximum quarterly whole-body exposure. 600 mremf. Maximum quarterly extremity exposure. 940 " shallower, beta "g. Licensee has implemented an ALARA program. ☒ Yes ☐ No

[35.50] [see Procedure No. 83822, "Radiation Protection"]

Remarks.

h. Radiation survey of unrestricted areas. ☒ Yes ☐ No
(20.201(b) to show compliance with 20.105(b)) [35.315(a)(4)];

[35.415(a)(4)]

Remarks.

9. (cont'd)

- (1) Record of surveys maintained. (☒) Yes () No
[20.401(b) to show compliance with 20.105(b)]
Remarks.

i. Radiation survey of storage and use areas:

- (1) Quarterly survey brachytherapy source storage. () Yes () No N/A
[35.59(h)]
- (2) Temporary implant patient release survey. () Yes () No
[35.404(a)]
- (3) Radiopharmaceutical and permanent implant patient release survey.
() Yes () No [35.75]
- (4) Radiopharmaceutical therapy room contamination survey.
() Yes () No [35.15(a)(5) and (7)]
- (5) Patient survey upon implant. () Yes () No [35.406(c)]
- (6) Radiopharmaceutical storage and laboratory use areas.
(☒) Yes () No [35.70]
Remarks.

- j. Record of survey maintained. (☒) Yes () No [35.70(h)]
Remarks.

Hot lab not recorded on weekly survey kit
weekly action level of 37, 312 dpm/10 cm² too high. NEU
Licensee will correct to add hot lab + lower action level.

- k. Inventory of brachytherapy sources after use. () Yes () No N/A
[35.406]
Remarks.

- l. Records maintained. () Yes () No [35.59(g)]; [35.406]

- m. Dose calibrator calibration and checks performed as follows:
Constancy (☒) Yes () No Accuracy (☒) Yes () No
Linearity (☒) Yes () No Geometric dependence (☒) Yes () No
[35.50]

10. PERSONNEL RADIATION PROTECTION - INTERNAL

- a. Potential for exposure of individuals to airborne radioactive material exists.
(☒) Yes () No
Remarks. *Exclusions in monthly Rms 684 + 784*

- b. Monitoring for airborne radioactivity conducted. (☒) Yes () No
[20.201(b) to show compliance with all sections of 20.103 and 35.90]
Remarks. *Thyroid
Effluents*

- (1) Records of monitoring maintained. (☒) Yes () No
[20.401(b) or L/C]
Remarks.

- c. Bioassay program implemented as described in correspondence with NRC.
(☒) Yes () No [35.315(a)(8)]

- d. Control of airborne radioactivity in accordance with 35.205.
(☒) Yes () No *Several holes in Mayan Rm (684 + 784) missing
flow charts in formation
Licensee will correct.*

11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

- a. Radioactivity in effluents to unrestricted areas. (☒) Yes () No
- b. Release in accordance with regulatory limits. (☒) Yes () No
[20.106(a)]
Remarks.

- c. State solid waste disposal method. *Deery + HTHS*

- d. State liquid waste disposal method. *Brigham + HTHS pickup*

11. (cont'd)

- e. Disposal of solid and liquid waste in accordance with regulatory requirements (decay in storage). (☒) Yes () No [35.92(a)]
Remarks.

Temporary waste storage area in waste bay
needs tighter supervisory control,
licensee will soon open central waste storage area.

- (1) Records of disposal. (☒) Yes () No [35.92(b)]
Remarks.

- f. Survey of waste prior to disposal. (☒) Yes () No
[20.201(b) to show compliance with 20.301 - 35.92(a)(2)]
Remarks.

- (1) Records of survey maintained. (☒) Yes () No [20.401(b)]
Remarks.

12. NOTIFICATIONS AND REPORTS

- a. Licensee in compliance with 10 CFR 19.13 (reports to individuals).
() Yes () No [19.13]
Remarks. NI

- b. Licensee in compliance with 10 CFR 20.405 (overexposures).
() Yes () No [20.405(a)]
Remarks. None

- c. Licensee in compliance with 10 CFR 20.403 (incidents).
(☒) Yes () No [20.403]
Remarks.

12. (cont'd)

- d. Licensee in compliance with 10 CFR 20.402 (theft or loss).

() Yes () No [20.402(a) or (b)]

Remarks.

None

- e. Licensee in compliance with reporting therapeutic misadministrations and taking corrective action. () Yes () No [35.33(a)(b)(d)]

Remarks.

N/A

- f. Licensee in compliance with reporting diagnostic misadministrations and taking corrective action as needed under conditions set forth in 10 CFR 35.33(c).

(☒) Yes () No

Remarks.

None

13. POSTING OF NOTICES

Notices to workers posted. (☒) Yes () No [19.11(a), (b), or (c)]

Remarks.

14. CONFIRMATORY MEASUREMENTS

- a. Measurements made by inspector. () Yes (☒) No

- b. Survey instrument and probe _____

NRC Serial No. _____

- c. Describe type and results of measurements and compare with licensee's measurements.

15. INDEPENDENT MEASUREMENTS

- a. Measurements made by inspector. (☒) Yes () No

- b. Survey instrument GM 923

NRC Serial No. NRC 923

- c. Describe type and results of measurements.

Marose Labs

*Rm 51684 732
784 746
624 719
631 716
645 884*

Penthouse I Sampling area

Buy to 15 mR/hr in hot sink (S-35)

DIANA

- Rm 1740 Spill observation of cleaning

- Rm 1740 Rm 1740 - 11/11/11

J F Buly

*Rm 526
" 503*

Ralsme Bldg

Irrad

" n i s u n

16. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203.

☒ Yes ☐ No [20.203]

Remarks.

17. LICENSE CONDITIONSa. All license conditions reviewed during inspection. ☐ Yes ☒ Nob. Activities were conducted in accordance with license conditions, except as noted elsewhere in this report. ☒ Yes ☐ No

Remarks:

18. BULLETINS AND INFORMATION NOTICESa. Bulletins and Information Notices issued during current year. N-I
List:b. Bulletins and Information Notices received by licensee. ☐ Yes ☐ No
Remarks.c. Licensee took appropriate action in response to Bulletins and Information Notices. ☐ Yes ☐ No
Remarks.19. TRANSPORTATION (10 CFR 71.5a and 49 CFR 171-178)a. License makes shipments of RAM?
If "Yes", complete the following items.Yes☒Violation?☐

b. Such shipments consisted of:

☒ radwaste
☐ sources/products
☐ other _____

19. (cont'd)

c. For radwaste, shipments are:

☐ by licensee, using common carrier☒ through Radwaste Brokername of Broker HCHS (Harvard Univ. Health Service)

d. Licensee is aware of 10 CFR 61:

Radwaste requirements for generators? *N/A*

()

()

Licensee has classified and characterized its radwaste? (20.311(d))

()

()

e. For shipments:

Licensee uses authorized packages?

()

()

[(173.415-16)]

Package type used. Steamer ticket

For DOT-7A, licensee has performance test records on file? [(173.415(a))]

()

()

For special form sources, licensee has performance tests records on file for each source design? [(173.47(a))]

{ }

{ }

Packages are properly labeled? [(172.403)]

{ }

{ }

[(173.441)]

{ }

{ }

Packages are properly marked? [(172.200)]

{ }

{ }

Proper shipping papers are prepared for each shipment? [(172.203(d))]

()

()

Remarks.

f. Does licensee make return shipments of radiopharmacy doses?

☒

()

(If Yes, does licensee assume responsibility for all shipper requirements?) *Yes* (If No, what arrangements/understanding have been made between licensee and radiopharmacy as to performance of shipper responsibilities?)
(Describe)

Remarks.

- Packages returned within confines of enclosed walkway for NM lab
 - Research waste picked up by Harvard Univ. Health Service

20. ITEMS OF NONCOMPLIANCE21. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

INSPECTION REPORT NUMBER 87-001

APPENDIX B - LICENSEE ACTIONS ON PREVIOUS INSPECTION FINDINGS

Licensee: Dana-Farber Cancer Inst

License No.: 20-19761-02

Identification and summary of action taken

Status

Report No.: 87-001 Type n/c: VIOLATION II Describe: Unsecured RAM in Nuclear Lab
Action taken: Push button lock installed
Verified lock installed/working

OPEN

CLOSED

Report No.: 87-001 Type n/c: VIOLATION IV Describe: Failure to report for hygiene
Action taken:

- Residents involved were notified they were in violation and requested for signs
- All residents in 10 minutes given general notice, threat to suspend
- Heads fixed with biohazard signs
- Assoc. Director & Research will personally follow-up on delinquents.

OPEN

CLOSED

Report No.: _____ Type n/c: _____ Describe: _____
Action taken: _____

OPEN

CLOSED

Report No.: _____ Type n/c: _____ Describe: _____
Action taken: _____

OPEN

CLOSED

Report No.: _____ Type n/c: _____ Describe: _____
Action taken: _____

OPEN

CLOSED

Report No.: _____ Type n/c: _____ Describe: _____
Action taken: _____

OPEN

CLOSED