MEDICAL

LICENSE FILE NO: 20-00289-07
20-00289-10

ATTACHED

DOCKET No. (s) 30-17705 ☒ Appendix A ☒ Appendix B ☐ Appendix C
D 30-17696

INSPECTION REPORT NO. 91-001

LICENSEE CONTACT: Phil Cobb

Name: New England Deaconess Hospital

TELEPHONE NO.: 617-732-7000

Address: 185 Pilgrim Road
Boston, MA 02215

LICENSE NO: 20-00289-07 PRIORITY: 1 Program Code: 2110
20-00289-10 PRIORITY: 3 Program Code: 03511, 03513
PRIORITY: Program Code:

INSPECTION DATE (s): 1/29-30/91 TYPE OF INSPECTION: ☐ SPECIAL ☐ ANNOUNCED

☒ ROUTINE ☒ UNANNOUNCED

☒ DAYSHIFT ☐ OTHER

SUMMARY OF FINDINGS AND ACTION

☐ NO NONCOMPLIANCE, CLEAR 591 ISSUED

☐ NO NONCOMPLIANCE, LETTER

☒ NONCOMPLIANCE, APPENDIX A

☐ ACTION ON PREVIOUS NONCOMPLIANCE, APPENDIX B

☐ NONCOMPLIANCE, 591 ISSUED

☒ SUPPLEMENTAL INFO, APPENDIX C

RECOMMENDATIONS
SEE APPENDIX C

☐ CHANGE PROGRAM CODE

☐ CHANGE PRIORITY TO:

☒ NEXT INSPECTION DATE: 1/92

PERSONS CONTACTED

Phil Cobb RSO
Eric Beaupre Assistant RSO
Eastern Barletta Sr. Health Physics Tech
Thomas Hall M.D. Nuclear Med. Physician
Linda Geneau Nuclear Med. Tech
Jim Edmonds Chief Nuclear Med Tech

Peter Thomas Ph.D. 1° Researcher
Arthur Caris Ph.D. 1° Researcher
Jorge B. Tower Senior V.P

INSPECTOR: Jorge P Tessen 2/8/91

APPROVED: F. H. Lewis 2/11/91

REGION I Form 198-C
(June '88)

D/92

Medical 1 License 20-00289-07
20-00289-10

1. ORGANIZATION

a. Organizational structure meets license requirements. (✓) Yes ( ) No [L/C]
Remarks.

b. Use supervised by authorized individuals. (✓) Yes ( ) No [35.22(b)(2)]
Remarks.

c. Radiation Safety Committee meets at quarterly intervals.
(✓) Yes ( ) No 3/90, 6/90 9/90 12/90, next increase for 3/91

(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.

e. Licensee uses the services of a visiting authorized user.
( ) Yes (✓) No [35.27(a)]

(1) Licensee has a copy of visiting authorized user license.
( ) Yes ( ) No [35.27(a)(2)] NA

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

f. License utilizes mobile nuclear medicine services. NA
( ) 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).
(✓) Yes ( ) No

2. INSPECTION HISTORY

Violations or deviations noted during last inspection conducted on 1/16-17/90
(✓) Yes ( ) No.

Response letter dated _____

(See Appendix B for details)

3. SCOPE OF PROGRAM

Briefly list medical procedures and their frequency.

60 patients per week; 3000 studies per year; ^{99m}Tc
hyperthyroid 2/wk
Techs 3 full time, 2 part time
Use generators & kits
2 thyroid CA in 1990
brachytherapy 20-30 per year)

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by license condition. (✓) Yes (~~✓~~) No ( ) N/A Tie down condition

b. Investigations or inspections conducted. (✓) Yes ( ) No
[35.21(a) and (b)(2)]
Remarks.

c. Records maintained. (✓) Yes ( ) No [35.21(b)(2)(xi)]
Remarks.

5. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

a. License referenced training program.

(1) Training program implemented. (✓) Yes ( ) No
Remarks.

(2) Retraining program implemented. (✓) Yes ( ) No
Remarks.
Annually

5. (cont'd)

b. Instruction to workers in accordance with 10 CFR 19.12.
(√) Yes ( ) No
Remarks.

*c. Describe the QA program to mitigate therapeutic misadministrations. no RX misadmins

(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 on the patient chart? ( ) Yes ( ) No

(3) Do technologists consult with the doctor if the prescription or other orders are unclear? ( ) Yes ( ) No
Remarks.

d. Followup on therapy or serious diagnostic misadministrations One DX misadministration (not reportable)

(1) 10 CFR 35.43 properly implemented? ( ) Yes ( ) No

(2) Was proper medical care given for the patient pursuant to the NRC 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
Remarks.

6. 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 NA

*Inspect when QA rule becomes final.

6. (cont'd)

t. Records of changes in procedures reviewed. ( ) Yes ( ) No NA
[35.31(b)]
Remarks.

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

(1) Describe individuals understanding of current procedures.
well trained & knowledgable Radiation Safety and other technical staff, researchers, techs and physicians

(2) Example of key procedures:
(a) ordering and accepting packages of RAM ✓
(b) general rules for safe use of RAM ✓
(c) emergency procedures
(d) survey procedures
(e) handling of volatile RAM (e.g., Xe-133, I-131) ✓
(f) precautions for use of RAM (sealed and unsealed) for therapy ✓
(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.

b. Isotope, chemical form, quantity and use as authorized.
(✓) Yes ( ) No [L/C]
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)]

[35.31(b)]
Remarks.

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

(1) Describe individuals understanding of current procedures.
well trained & knowledgeable Radiation Safety and other technical staff, researcher, techs and physicia

(2) Examples of key procedures:
(a) ordering and accepting packages of RAM ✓
(b) general rules for safe use of RAM ✓
(c) emergency procedures
(d) survey procedures ✓
(e) handling of volatile RAM (e.g., Xe-133, I-131) ✓
(f) precautions for use of RAM (sealed and unsealed) for therapy ✓
(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.

b. Isotope, chemical form, quantity and use as authorized.
(✓) Yes ( ) No [L/C]
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)]

7. (cont'd)

e. Tests required by regulations.

(1) molybdenum-99 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. performed as req'd.

f. Inventory of sealed sources.

(1) Inventory of Group VI sources. (✓) Yes ( ) No [35.59(g)]
Dates:

(2) Inventory of calibration sources. (✓) Yes ( ) No [35.59(g)]
Dates:

g. Areas for storage and use of radioactive materials.

N/C (1) Method used to prevent an unauthorized individual adequate storage security

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

Remarks.

(3) Area wipe 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.

7. (cont'd)

(2) Capability of radiation survey instruments is adequate for program.
(✓) Yes ( ) No
Remarks.

MC (3) Calibration of survey instruments required. ( ) Yes (✓) No

(a) Performed as required. ( ) Yes ( ) No [35.50]
Dates and Remarks.
Keithley Eutie Pie due for calibration 2-15-90.

(4) Records of calibration maintained for 3 years. [35.50(e)]
(X) Yes ( ) No

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

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

(a) Where stored? Security? [L/C] Adequate

(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.

8. (cont'd)

(e) 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 _____ Frequency monthly

b. Reports reviewed by NSO? yes, monthly Others RSC ? Frequency Yearly
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period 1/90 to 11/90

d. NRC forms or equivalent.

(1) NRC-4: ( ) Yes ( ) No Complete: ( ) Yes ( ) No
Necessary ( ) Yes ( ) No

(2) NRC-5: ( ) Yes ( ) No Complete: ( ) Yes ( ) No
[20.401(a)]
Remarks.

e. Maximum quarterly whole-body exposure. less than ALARA } discussed at Radiation Safety Committee Meetings

f. Maximum quarterly extremity exposure. less than ALARA }

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
[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 [35.315(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.

k. Inventory of brachytherapy sources after use. (✓) Yes ( ) No
[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.

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

(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

11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. Radioactivity in effluents to unrestricted areas. ( ) Yes ( ) No
no sewer disposal

b. Release in accordance with regulatory limits. (✓) Yes ( ) No
[20.106(a)]
Remarks.

c. State solid waste disposal method. DIS & ADCO

d. State liquid waste disposal method. ~~[illegible]~~

11. (cont'd)

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

(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.

b. Licensee in compliance with 10 CFR 20.405 (overexposures).
( ) Yes ( ) No [20.405(a)] NA No overexposure
Remarks.

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

12. (cont'd)

c. Licensee in compliance with 10 CFR 20.402 (theft or loss).
( ) Yes ( ) No [20.402(a) or (b)]
Remarks. no theft or loss of material

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

f. License 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.

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. Comparable to licensee's

15. INDEPENDENT MEASUREMENTS

a. Measurements made by inspector. (✓) Yes ( ) No

b. Survey instrument GM
NRC Serial No. _____

c. Describe type and results of measurements.
max hot lab. exposure rate
15 mR/hr at generator

16. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203.
(✓) Yes ( ) No [20.203]
Remarks.
Failure to post "Caution, Radioactive Material Sign" on doorway ē access to hot lab and corridor in which patients are injected
And where general employees use, ie walkway is not posted.

17. LICENSE CONDITIONS

a. All license conditions reviewed during inspection. (✓) Yes ( ) No

b. Activities were conducted in accordance with license conditions, except as noted elsewhere in this report. (✓) Yes ( ) No
Remarks:

18. BULLETINS AND INFORMATION NOTICES

a. Bulletins and Information Notices issued during current year.
List: 90-71 Effective use of RSC to exercise control over medical use programs

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)

	Yes	Violation?
a. License makes shipments of RAM? If "Yes", complete the following items.	(✓)	( )

b. Such shipments consisted of:
(✓) radwaste to ADCO
( ) sources/products
(✓) other generators to Beth Israel ē transportation records as reqd.

19. (cont'd)

c. For radwaste, shipments are:
( ) by licensee, using common carrier
(✓) through Radwaste Broker
name of Broker ADCO

d. Licensee is aware of 10 CFR 61: NI
Radwaste requirements for generators? ( ) ( )
Licensee has classified and characterized its radwaste? (20.311(d)) ( ) ( )

e. For shipments:
Licensee uses authorized packages? ( ) ( )
[(173.415-16)]
Package type used. _____
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?) (If No, what arrangements/understanding have been made between licensee and radiopharmacy as to performance of shipper responsibilities?)
(Describe)
Remarks.

20. ITEMS OF NONCOMPLIANCE

20.203(e) failure to post "Caution, Radioactive material"
~~Security~~
2- survey calibration

21. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

INSPECTION REPORT NUMBER 91-01

APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

LICENSEE: New England Deaconess License No. 20-00289-07 20-00289-10

Reference	Basis for noncompliance
Report item ~~7g~~	
10 CFR 20.205e	~~Unsecured~~ material in an unrestricted area. Failure to post "Caution, Radioactive Material" Sign
Lic Cond	
Type n/c III ↓ IV	
Report item 7h	
10 CFR 35.51	Failure to calibrate survey instrument Annually as per 10 CFR 35.51.
Lic Cond	
Type n/c	
Report item	
10 CFR	
Lic Cond	
Type n/c	
Report item	
10 CFR	
Lic Cond	
Type n/c	
Report item	
10 CFR	
Lic Cond	
Type n/c	
Report item	
10 CFR	
Lic Cond	
Type n/c	

INSPECTION REPORT NUMBER 91-01

APPENDIX B - LICENSEE ACTIONS ON PREVIOUS INSPECTION FINDINGS

Licensee: New England Deaconess License No.: 20-00289-01 20-00289-10

Identification and summary of action taken	Status
Report No.: 90-01 Type n/c: SL IV Describe: Daily Constancy Action taken: Daily constancy performed as required.	OPEN CLOSED
Report No.: 90-01 Type n/c: SL IV Describe: Daily Survey Action taken: Daily surveys performed as required.	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

INSPECTION REPORT NUMBER _____

APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: _____ License No.: _____

( ) Uncorrected/repeated noncompliance

( ) Unusual occurrence, conditions, etc.

( ) Basis for change of Category or Priority

( ) Unresolved items

( ) Inspector's comments