MEDICAL

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

ATTACHED

DOCKET No. (s) 030-01868
030-17696

[X] Appendix A [ ] Appendix B [ ] Appendix C

INSPECTION REPORT NO. 88-001

LICENSEE CONTACT: Philip Cobb

Name: New England Deaconess Hospital

TELEPHONE NO.: 617-732-7000

Address: 185 Pilgrim Road
Boston, Massachusetts 02215

LICENSE NO: 20-00289-07 PRIORITY: 2 G1 Program Code: 02110
20-00289-10 PRIORITY: 3 E Program Code: 03511, 03510
PRIORITY: Program Code:

INSPECTION DATE (s): 6/14/88 6/15/88 TYPE OF INSPECTION: [ ] SPECIAL [ ] ANNOUNCED
[X] ROUTINE [X] UNANNOUNCED
[X] DAYSHIFT [ ] OTHER

SUMMARY OF FINDINGS AND ACTION

[ ] NO NONCOMPLIANCE, CLEAR 591 ISSUED

[ ] ACTION ON PREVIOUS NONCOMPLIANCE, APPENDIX B

[X] NO NONCOMPLIANCE, LETTER

[ ] NONCOMPLIANCE, 591 ISSUED

[X] NONCOMPLIANCE, APPENDIX A

[ ] SUPPLEMENTAL INFO, APPENDIX C

RECOMMENDATIONS
SEE APPENDIX C

[ ] CHANGE PROGRAM CODE

[ ] CHANGE PRIORITY TO:

[X] NEXT INSPECTION DATE: 6/90

PERSONS CONTACTED

Philip Cobb, RSO
Lou Emond, Supervisor Nuclear Medicine
Robert Pence, Administrator

INSPECTOR: S. Wong / Rajendran

APPROVED: [signature] 7/25/88

REGION 1 Form 198-C
(June '88)

D/86

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.
All users are authorized by RSC

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.

e. Licensee uses the services of a visiting authorized user.
( ) Yes (✓) Nc [35.27(a)]

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

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

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).
(✓) Yes ( ) No

2. INSPECTION HISTORY

Violations or deviations noted during last inspection conducted on April 9, 1986
(✓) Yes ( ) No.

Response letter dated June 27, 1986
(See Appendix B for details)

3. SCOPE OF PROGRAM

Briefly list medical procedures and their frequency.

@ 15 patients per day in Nuclear Medicine
40% of these are Cardiology studies
40% bone scans, 20% others (Thyroid uptakes, Lung scans)
3 staff tech, 1 admin. personnel
3 authorized users (N.M) Dr Thomas Hill, Dr Judy Kelly, Dr Gramm
1 Chief of NM (Dr Thomas Hill

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by license condition. ( ) Yes (X) No ( ) N/A

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

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

5. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

a. License referenced training program.

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

(2) Retraining program implemented. (X) Yes ( ) No
Remarks.
Yearly by RSO

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.

(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 N/A NO therapy - Referred to medical consultant

(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

*Inspect when QA rule becomes final.

6. (cont'd)

b. Records of changes in procedures reviewed. ( ) Yes ( ) No [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.
Knowledgable & well-trained workers

(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 autnorized. (✓) 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 purformed as required. (✓) Yes ( ) No [35.59(b)]
Dates and Remarks.

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.

(1) Method used to prevent an unauthorized individual OK

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

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.
20-30 survey instruments
Calibrated in house

7. (cont'd)

(2) Capability 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

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

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

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

(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 RSO? yes Others RSC ¼ Cyg ?
Frequency monthly
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period 4/86 — 5/87
to _____

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. 7 (in regulatory limits)

f. Maximum quarterly extremity exposure. 9 (in regulatory limits)

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. DS
( ) 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

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

c. State solid waste disposal method.

d. State liquid waste disposal method.

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)]
Remarks. No overexposures

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.
No theft or loss of RAM

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

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 Hot Lab - 0.08 mR/hr Storage (generator) floor - 0.2 mR/hr

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 Ludlum 14C
NRC Serial No. NRC 0.9614

c. Describe type and results of measurements.

16. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203.
(✓) Yes ( ) No [20.203]
Remarks.

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 N.I.

a. Bulletins and Information Notices issued during current year.
List:

b. Bulletins and Information Notices received by licensee. ( ) Yes ( ) No N.I
Remarks.

c. Licensee took appropriate action in response to Bulletins and Information Notices. ( ) Yes ( ) No N.I
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
( ) sources/products
(✓) other generators (Mo99/Tc99M)
Spent generator to Beth Israel Hospital on Fridays (P.M)
to cover weekends at " " "

19. (cont'd)

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

d. Licensee is aware of 10 CFR 61: N.I
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

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

INSPECTION REPORT NUMBER 88-001

APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

LICENSEE: New England Deaconess Hospital License No. 22-00289-07
20-00289-10

Reference	Basis for noncompliance
Report item	Clear
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	
Report item	
10 CFR	
Lic Cond	
Type n/c	
Report item	
10 CFR	
Lic Cond	
Type n/c	

INSPECTION REPORT NUMBER ___ _____

APPENDIX B - LICENSEE ACTIONS ON PREVIOUS INSPECTION FINDINGS

Licensee: New England Deaconess Hospital License No.: _____

Identification and summary of action taken	Status

Report No.: 86-01 Type n/c: _____ Describe: Shipping to Transport

Action taken:

Procedure revised & proper labeling & description on shipping papers

OPEN
CLOSED

Report No.: 86-01 Type n/c: _____ Describe: Dose calibrator

Action taken:

Were checked against calibration source & performed to determine ± 5% of daily constancy

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

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

DOCKET NUMBER: 30-17696

	REPORT NUMBER	STATUS	DATE OPEN	DATE CLOSED	REVIEWER NAME	OPTION	CLOSING REFER
1	88-001	CLOSED	06/14/88	06/15/88	L.M.TRIPP	VIOL	88-001

ITEM: CLEAR

6/87