MEDICAL

LICENSE FILE NO: 20-00742-18
20-00742-19 ATTACHED

DOCKET No. (s) 030-09062
030-22193

☐ Appendix A ☐ Appendix B ☐ Appendix C

INSPECTION REPORT NO. 89-001

LICENSEE CONTACT: Rosemary Kennedy

Name: Beth Israel Hospital

TELEPHONE NO.: 617-735-2510

Address: 330 Brookline Ave
Boston MA 02215

LICENSE NO:	20-00742-18	PRIORITY:	1	Program Code:	02110
	20-00742-19	PRIORITY:	3	Program Code:	3510
		PRIORITY:		Program Code:	

INSPECTION DATE (s): 5/23&24/89 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: 5/90

PERSONS CONTACTED

Rosemary Kennedy, RSO
John Kurkomelis, Assistant RSO
Grace Jansina, Chief NMT
Mel Weiner, Assoc. Dir. of Hosp.
Lisa Gjedraitis, Survey Tech
Lisa Olson, Tech

Chairman RSC

INSPECTOR: J M Tripp

APPROVED: M. Stanley

REGION 1 Form 198-C
(June '88)

D/69

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 RSC meets ~~once~~ every 2 months

(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.
( ) 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 _____
( ) Yes ( ) No. NA Last inspection on 1/2/87 was clear

Response letter dated _____
(See Appendix B for details)

3. SCOPE OF PROGRAM

Briefly list medical procedures and their frequency.

@ 20 Dx procedures/day
Sporadic I-131 Ca Rx / up to several/month
Several brachytherapy patients per year

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by license condition. (X) Yes ( ) No ( ) N/A
Through monthly audits performed by H-P staff
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.
Initial training provided by Harvard - Tests given, records maintained
Annual retraining

(2) Retraining program implemented. ( ) Yes ( ) No
Remarks.
Annual retraining by H-P staff at BIH

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 therapeutic misadministration

(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 NA no serious Dx misadmin's.

(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 N/A

*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.
Knowledgeable and well trained staff

(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.
Amendment request is presently being reviewed to add research space

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)]

5. (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.
Generators are only used on weekends ~~unless~~ unit doses are used

(4) Leak tests. (✓) Yes ( ) No

(5) Leak tests performed 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 ✓

(2) Radioactive material secured to prevent unauthorized removal from an unrestricted area. ( ) Yes ( ) 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.

Capacity of radiation survey instruments adequate for program.
Remarks.

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

(a) Performed as required. (✓) Yes ( ) No [35.50]
Dates and Remarks.

Calibrations by Harvard group

(4) Records of calibration maintained for 3 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] Access to security

(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 Landauer Frequency monthly

b. Reports reviewed by RSO? monthly Others _____?
Frequency _____
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period 1/87 to 2/89.

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. < ALARA 1 (except Fluoroscopy labs)

f. Maximum quarterly extremity exposure. < ALARA 1

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.

h. Records

(1) Record of surveys maintained. ( ) Yes ( ) No
[20.401(a) to show compliance with 20.105(a)]
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.
Inventory and survey performed by Joint Center

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.
(X) Yes ( ) No
Remarks. Xenon
room at neg. pressure (checked 6 mo intervals
traps monitored
Alarm

b. Monitoring for airborne radioactivity conducted. (X) 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. picked up by Harvard
records maintained

d. State liquid waste disposal method. some ~~Urine~~ drain
disposal, records maintained
(to show compliance w Part 20)

... (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.
no incidents

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 of loss of materials

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 NRC notified (see file)
Remarks.
1 Dx misadministration 8/5/87 Report late
Human error. Labelling of vials was correct. Tech drew up dose from wrong vial. No misadministration since investigated by RSC. Technical meeting of tech emphasizing the careful identification of radiopharmaceutical vials. Corrective items OK

13. POSTING OF NOTICES

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

14. CONFIRMATORY MEASUREMENTS

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

b. Survey instrument and probe GM
NRC Serial No. 000923

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

15. INDEPENDENT MEASUREMENTS

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

b. Survey instrument 000873 GM
NRC Serial No. _____

c. Describe type and results of measurements.
background outside waste storage area

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 NC

a. Bulletins and Information Notices issued during current year.
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)

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

b. Such shipments consisted of:
(✓) radwaste
( ) sources/products
( ) other _____

19. (cont'd)

c. For radwaste, shipments are:
( ) by licensee, using common carrier
( ) through Radwaste Broker
name of Broker Hazard picks up waste

d. Licensee is aware of 10 CFR 61:

Radwaste requirements for generators?	(Y)	( )
Licensee has classified and characterized its radwaste? (20.311(d))	( )	( )

e. For shipments:

Licensee uses authorized packages? [(173.415-16)]	( )	( )
Package type used. yes		
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)]	( )	( )
kages are properly marked? [172.200)]	( )	( )
oper 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

APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

LICENSEE: _____ License No. _____

Reference	Basis for noncompliance
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	clear
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: _____ License No.: _____

Identification and summary of action taken	Status
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
Report No.: _____ Type n/c: _____ Describe: _____ Action taken:	OPEN CLOSED
Report No.: _____ Type n/c: _____ Describe: _____ Action taken:	OPEN CLOSED

clear

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 1
OPEN ITEMS TRACKING SYSTEM

DOCKET NUMBER: 30-09062

	REPORT NUMBER	STATUS	DATE OPEN	DATE CLOSED	REVIEWER NAME	OPTION	CLOSING REFER
1	87-01	CLOSED	01/02/87	01/02/87	WURTZ	VIOL	87-01
	ITEM: CLEAR - 59:						
2	86-01	CLOSED	02/01/86	01/02/87	JOHANSEN	VIOL	87-01
	ITEM: APPROPRIATE PROTECTION MEASURES WHEN HANDLING RAM WERE NOT USED. (TONGS AND PLEXIGLASS)						
3	87-198	CLOSED	11/20/87	05/24/88	BETSY ULLRICH	LER	88-001
	ITEM: TWO (2) DIAGNOSTIC MISADMINISTRATIONS						