MEDICAL LICENSE TITLE NO: [illegible]

ATTACHED

DISTRICT No.: [illegible] ☐ Appendix A ☐ Appendix B ☒ Appendix C

[illegible]

INSPECTION REPORT NO. [illegible] LICENSEE CONTACT: Ron Anoling

Name: Childrens Hospital (Boston) TELEPHONE NO.: (617) 735-6000

Address: 300 Longwood Avenue Enders Bldg SB-22, Rads Control Unit
Boston, Massachusetts 02115

LICENSE NO: 20-09568-17	PRIORITY: 1	Program Code: 61
20-09568-18	PRIORITY: 3	Program Code: E
	PRIORITY:	Program Code:

INSPECTION DATE (s): June 14-15, 1989 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: 6/90

PERSONS CONTACTED

*E. Travis Allen - Chairperson RSC
*P. Armington - RSO
*Susan Fantaleoni - Director of Research Administration
Leta Bradford - Health Physics Technician
Robert Zimmerman - Medical Physicist
* present at exit

Raoul Davis - Chief Nuclear Med Tech Technical administration
James Olanski - Nuclear Med Tech
Mark Bigoness - Health Physics Tech
Numerous researchers, principal investigators, and other laboratory personnel were also interviewed

INSPECTOR: J Miller 7/19/89 A. Kilmood 7/21/89

APPROVED: J Piccone 8/5/89

REGION 1 Form 198-C
(June '88)

D/140

1. ORGANIZATION

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

Board of Trustees
President
Director of Research Administration
Dr. Treves, Director-Division of Nuclear Medicine RSC Chairman
RSO
RSC Chairman also reports directly to Medical Staff Executive Committee

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

Dr. Treves is principal physician
Dr. Sommerville left institution May 1, 1989, has been replaced by Dr. [illegible]
Radiology resident works under Treves supervision
Physicians from Dana Farber & Brigham & Womens cover for Treves in his absence under his supervision

c. Radiation Safety Committee meets at quarterly intervals.
(✓) Yes ( ) No RSC is active, they meet [illegible] times [illegible] year

(1) Membership in accordance with 35.22(a)(1)] ( ) Yes ( ) No
Remarks.

RSC Chair
[illegible]
Administrator
[illegible]

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

records were reviewed and pertinent subject matter was discussed at meetings

(3) Consultants. (✓) Yes ( ) No
Remarks.

Harvard Services. RSO is an employee of the "Harvard" consulting service and he splits his time between Childrens Hospital & Dana Farber Cancer Institute

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)]

(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).
( ) Yes ( ) No

Annual review of program performed by RSO ~~[illegible]~~
[illegible] by RSC

2. INSPECTION HISTORY

Violations or deviations noted during last inspection conducted on August 5th - 7th
(X) Yes ( ) No.

Response letter dated March 21, 1985
(See Appendix B for details)

3. SCOPE OF PROGRAM

Briefly list medical procedures and their frequency.

≈ 3,000 procedures/year no brachytherapy radiopharmaceutical therapy I-131 for (1 or 2/year)
thyroid carcinoma Xenon-133 50 scans/year
Radiopharmaceuticals are purchased from Brigham & Womens Hospital
multi-dose vials of Tc-99m & emergency generators for weekends & night
40-45 principal investigators → 100-110 laboratories
≈2 Cr-51 in radiosynthesis 5-35 P-32 millicurie quantities max, I-125 millicurie
quantities only in iodination procedures (in development
some need), ≈ 2 or 3 iodinations/day

4. INTERNAL AUDITS OR INSPECTIONS

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

b. Investigations or inspections conducted. ( ) Yes ( ) No
[35.21(a) and (b)(2)] Remarks.
Health Physics Tech performs laboratory inspection at
the same time that surveys are performed. Tech reports non-compliance
or unsatisfactory laboratory conditions to the RSO. A formal
notice of violation is issued by RSO. PI is required to respond
in writing and describe corrective action implemented. Inspectors reviewed
internal NOVs and did not
identify one case in which PI failed to respond to RSO. Recurrent
violations are addressed by RSC. RSO performs laboratory inspection/review
before PI authorizations are issued. Permits are issued for 2 years
and renewed. RSO has recently met with 5 PIs prior to renewal to
discuss violations identified in
their laboratory. Licensee has an
effective self identification & correction
program.

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.
Inspectors toured dozens of laboratories and interviewed personnel.
Individuals consistently stated that they had received the required
formal training, were familiar with the radio monitoring equipment
waste disposal process, and procedures to maintain their exposures "ALARA"

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

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. N/I

(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

(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

Procedures were as submitted in license application

*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.

(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.
Nuc Med Techs use "emergency" generator @ nights & weekends. Mony breakthrough test was performed, records maintained. Records indicated no evidence of a molybdenum-99 breakthrough

(4) Leak tests. (✓) Yes ( ) No

(5) Leak tests performed as required. (✓) Yes ( ) No [35.59(b)]
Dates and Remarks.
Inspectors reviewed records of leak tests performed on calibration sources as well as irradiators. Records indicate sources are not leaking

f. Inventory of sealed sources.

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

(2) Inventory of calibration sources. ( ) Yes ( ) No [35.59(g)]
Dates: done when leak tested

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.
Security was adequate

(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.

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

(a) Performed as required. (✓) Yes ( ) No [35.50]
Dates and Remarks.
Survey meters available were commensurate with the isotopes and quantities in program. Every survey meter inspected had a current calibration sticker

(4) Records of calibration maintained for 2 years. [35.50(e)] NI
( ) 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] locked in hot lab

(b) Survey of incoming packages. ( ) Yes ( ) No [20.205(b)(1)]
Remarks.

(1) Record of survey. ( ) Yes ( ) No [20.401(b)] in Nuclear Medicine ✓
Remarks.
NC Packages containing radioactive material, including generators, were not surveyed @ 3ft and on surface of the package. RSO stated that Packages should be surveyed externally as well as checked with swipe for contamination.

(c) Procedure for opening packages. (✓) Yes ( ) No [20.205(d)]
Remarks.
Established, but not followed

(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? Dosimetry records were reviewed by RSO Others _____?
Frequency monthly
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period 6/87 to 4/89

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. According to dosimetry records, no exposures in excess of regulatory or ALARA limits have been received.

e. Maximum quarterly whole-body exposure. _____

f. Maximum quarterly extremity exposure. _____

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.
~~Close~~

Observed nuclear med tech inject a patient.
Syringe was appropriately labelled and assayed prior administration.
Individual used disposable gloves, wore a whole body badge, finger dosimeter, and a lab coat and also used a syringe shield
Contaminated refuse generated during procedure was disposed of properly.

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 NA
[35.59(h)]

(2) Temporary implant patient release survey. ( ) Yes ( ) No NA
[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)] NA

(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 NA
[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]
Annual accuracy last performed 4/4/89 @ Cs-137 18 μCi, Ba-133 193 μCi, Co-57 3.1 mCi. All within ±5%
(NC) Linearity tests performed using calicheck, done quarterly. Do not always cover full range of activities assayed.
e.g. 3/2/88 max activity 115 mC. → on 5/18/88 assayed 150 mC. of I-131
2/1/88 max activity 635 μC. → routinely assayed millicurie quantities

10. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive material exists.
( ) Yes ( ) No
Remarks.
All iodinations are performed in a dedicated fume hood in the Radiation Safety Dept.

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.
Randomly selected 12-15 researchers who performed iodinations @ millicurie quantities of I-125 => all had their thyroids monitored within 30 days. Records indicated no significant uptake. RSO sent reminders to researchers @ 215 days post iodination a written reminder to have thyroid monitored.

c. Bioassay program implemented as described in correspondence with NRC.
( ) Yes ( ) No [35.315(a)(8)]
N/C Physician who administered 150 mCi of I-131 in liquid form for thyroid carcinoma ~~[illegible]~~ on 11 May 1988 failed to have his thyroid monitored.

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.
Licensee maintains records of stack monitoring performed @ iodination hood. Records indicated no release in excess of regulatory limit (MPC for I-125

c. State solid waste disposal method. Decay in storage
Brokered < Harvard
Commercial Contractor

d. State liquid waste disposal method. Sink disposal

Records of waste manifests were on file and in order

b. continued.
Liquid releases are made from sinks in laboratory. Records are maintained above sinks and forwarded to the Rad Safety Office. Effluent releases are compiled by RSO. Records indicated no releases in excess of Regulatory limits. Sinks were monitored by inspectors who found no evidence that disposals were being made without an evaluation or record.

11. (cont'd)

e. Disposal of solid and liquid waste in accordance with regulatory requirements (decay in storage). ( ) Yes ( ) No [35.92(a)]
Remarks.
Materials held for decay-in-storage were surveyed prior to release to the normal trash streams. Records were maintained.

(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.
PI's are responsible for bringing waste to a central repository
HP technician surveys waste bags to ensure H3 & C-14 labeled
contain only those isotopes & not P32 or gamma emitter
Unlabeled waste bags are not accepted by H.P technician

(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). NA
( ) Yes ( ) No [20.405(a)]
Remarks.

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

The RSO reported the following:

nce ast nspection
- No misadministrations
- No stolen or lost material
- No significant contamination incidents or reasons to believe and individual had been exposed to radiation in excess of Regulatory Limits.

12. (cont'd)

d. Licensee in compliance with 10 CFR 20.402 (theft or loss). NA
( ) Yes ( ) No [20.402(a) or (b)]
Remarks.

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

f. License in compliance with reporting diagnostic misadministrations and taking corrective action as needed under conditions set forth in 10 CFR 35.33(c). NA
( ) Yes ( ) No
Remarks.

13. POSTING OF NOTICES

Notices to workers posted. (✓) Yes ( ) No [19.11(a), (b), or (c)]
Remarks.
Inspectors surveyed around Gammacell 40 -> max 0.1 mR in hr
Blood Bank Irradiator -> max 0.2 mR in hr
Both irradiators are secured from unauthorized use and the operating key is maintained by a responsible individual
RSO stated that only the manufacturer performs maintainence on irradiators.

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 _____
NRC Serial No. _____

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
The inspectors reviewed all license conditions that affect health & safety

b. Activities were conducted in accordance with license conditions, except as noted elsewhere in this report. ( ) Yes ( ) No
Remarks:
Animal ~~research~~ using isotopes, but researchers are responsible for caring for animals and cleaning cages. Animal carcasses are disposed of through Harvard

18. BULLETINS AND INFORMATION NOTICES NI

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 Harvard, Radiac, etc.

d.	Licensee is aware of 10 CFR 61: Radwaste requirements for generators?	( )	( ) NI
	Licensee has classified and characterized its radwaste? (20.311(d))	( )	( )
e.	For shipments: Licensee uses authorized packages? [(173.415-15)]	( )	( )
	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

APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

LICENSEE: The Childrens Hospital - Boston License No. 20-09568-17 20-09568-18

Reference	Basis for noncompliance
Report item 8 10 CFR 20.205(d) Lic Cond Type n/c IV	Failure to follow established procedures for safely opening incoming packages containing licensed material. Specifically, external radiation measurements were not made 3 feet from the package and on the surface of the package
Report item 9 10 CFR Lic Cond 23 Type n/c IV	Failure to test the dose calibrator over the entire range of activities that it is used to assay.
Report item 9 10 CFR Lic Cond 23 Type n/c IV	Failure to perform a linearity test on a replacement dose calibrator prior to placing into service
Report item 10 10 CFR 20.201 Lic Cond Type n/c IV	Failure evaluate (perform a bioassay) the uptake of a physician who administered 150 mCi of I-131 in liquid form to a patient
Report item 10 CFR Lic Cond Type n/c	
Report item 10 CFR Lic Cond Type n/c	

INSPECTION REPORT NUMBER 89-001

APPENDIX B - LICENSEE ACTIONS ON PREVIOUS INSPECTION FINDINGS

Licensee: The Children's Hospital - Boston License No.: 20-09568-17, 20-09568-18

Identification and summary of action taken	Status
Report No.: 89-01 Type n/c: IV Describe: Failure of researchers to have their thyroids monitored 30 days after performing iodinations Action taken: RSO sends researchers a reminder two weeks after performing an iodination to have their thyroid monitored. Inspectors reviewed a representative sample of researchers who had performed iodinations and all of them had had their thyroids counted within	OPEN CLOSED
Report No.: 89-01 Type n/c: IV Describe: Failure to calibrate 30 day survey meters annually Action taken: The survey meters in nuclear medicine and other survey meters in the research facilities observed by the inspectors all had current calibration stickers and had been calibrated or checked/tested in accordance with license requirements	OPEN CLOSED
Report No.: 89-01 Type n/c: IV Describe: Failure to wear a lab coat while handling radioactive material Action taken: All individuals observed handling radioactive material were observed to be wearing a lab coat	OPEN CLOSED
Report No.: 89-01 Type n/c: IV Describe: Radiation Control authorizing purchases in excess of the permit holders limit. Action taken: The inspectors reviewed purchased orders against the Principal investigator permit and found that orders were within the authorized possession limit and for the isotopes authorized. In one case, an order was placed for 3 mCi where 2 mCi of the same isotope was authorized, but the inspectors did not feel this was a problem with the program and does not impact health & safety	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 87-

APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: Children's Hospital - Boston License No.: 20-09568-17

( ) Uncorrected/repeated noncompliance

( ) Unresolved items

( ) Unusual occurrence, conditions, etc.

(X) Inspector's comments

( ) Basis for change of Category or Priority

RSO is employed by the Harvard Consulting Group and he splits his time between Children's Hospital & Dana Farber Cancer Institute. He is supported by one health physics technician who performs laboratory surveys and inspections at both Children's Hospital & Dana Farber. At the exit, Children's Hospital expansion (≈ 100 laboratories) was discussed and participants stated that the licensee plans to hire a full time RSO. The expanded scope of work will need the support of a full time RSO and the increased workload on the Radiation Safety Staff ~~should be monitored by the NRC Staff~~ and the Staff ability to cover this expanding program should be monitored by NRC Staff.

throughout the site

Inspectors observed ≈ 12 compressed gas cylinders that were not anchored to the wall or were anchored below the center of gravity and ∴ could fall and injure someone. This finding was discussed at the exit interview and the licensee's management agreed to follow-up.

U.S. NUCLEAR REGULATORY COMMISSION
REGION 1
OPEN ITEMS TRACKING SYSTEM

DOCKET NUMBER: 03-02021

	REPORT NUMBER	STATUS	DATE OPEN	DATE CLOSED	REVIEWER NAME	OPTION	CLOSING REFER
1	87-001	CLOSED	08/06/87	06/20/89	DARDEN, TERESA	VIOL	89-001
	ITEM: FAILURE TO WEAR LAB COATS AS REQUIRED						
2	87-001	CLOSED	08/06/87	06/20/89	DARDEN, TERESA	VIOL	89-001
	ITEM: FAILURE TO CALIBRATE SURVEY METER AS REQUIRED.						
3	87-001	CLOSED	08/06/87	06/20/89	DARDEN, TERESA	VIOL	89-001
	ITEM: FAILURE TO PERFORM BIOASSAYS WITHIN THIRTY DAYS OF HANDLING IODINE AS REQUIRED.						
4	87-001	CLOSED	08/06/87	06/20/89	DARDEN, TERESA	VIOL	89-001
	ITEM: AUTHORIZED USER EXCEEDED POSSESSION LIMITS FOR PERMIT.						
5	89-001	OPEN	06/20/89	/ /	MILLER&KIRKWOOD	VIOL	
	ITEM: 20.201 FOR 20.105 PHYSICIAN ADMIN 180 MCI OF I131 IN LIQUID FORM, NO CLOSURE						
6	89-001	OPEN	06/20/89	/ /	MILLER&KIRKWOOD	VIOL	
	ITEM: 20.206 FAILURE TO FOLLOW SAFE OPENING PROCEDURES SURVEYS AT 0 FT & SURFACE NOT PERFORMED						
7	89-001	OPEN	06/20/89	/ /	MILLER&KIRKWOOD	VIOL	
	ITEM: LINEARITY TEST NOT PERFORMED OVER FULL RANGE OF ACTIVITIES						
8	89-001	OPEN	06/20/89	/ /	MILLER&KIRKWOOD	VIOL	
	ITEM: LINEARITY TEST NOT PERFORMED ON 'LOWNERY' DOSE CALIBRATOR AT TIME OF INSTALLATION						

AUG 08 1989

Docket Nos. 030-08021
030-11864

License Nos. 20-09568-17
20-09568-18

The Children's Hospital - Boston
ATTN: Susan Pantaleoni
Director for Research
Administration
300 Longwood Avenue
Boston, Massachusetts 02115

Gentlemen:

Subject: Routine Inspection No. 89-001

On June 19-20, 1989, J. Miller and A. Kirkwood of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC licenses. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you and others of your staff at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed as Appendix A and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

OFFICIAL RECORD COPY

MA. DI. CHILDRENS HOSP - 0'
07/19/89

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REGION I

D/161

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
Josephine M. Piccone, Ph.D.

for Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

Enclosure:
Appendix A, Notice of Violation

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts
R. Amoling, Radiation Safety Officer
S. Treves, M.D., Chairman of Radiation Safety Committee

bcc:
Region I Docket Room (w/concurrences)
Management Assistant, DRMA

RI:DRSS	RI:DRSS	RI:DRSS
Kirkwood/pmb	Miller	for Shanbaky
07/25/89	07/21/89	07/25/89

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07/19/89

APPENDIX A

NOTICE OF VIOLATION

The Children's Hospital - Boston
Boston, Massachusetts 02115

Docket No. 030-08021
License No. 20-09568-17

As a result of the inspection conducted on June 19-20, 1989, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1988), the following violations were identified:

A. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, surveys were not made to determine that an individual was not exposed to airborne concentrations exceeding the limits specified in 10 CFR 20.103. Specifically, on May 18, 1988, a physician administered 150 millicuries of iodine-131 in liquid form to a therapy patient and failed to have a thyroid bioassay.

This is a Severity Level IV violation. (Supplement IV)

B. 10 CFR 20.205(d) requires that each licensee establish and maintain procedures for safely opening packages in which licensed material is received and ensure that such procedures are followed.

Contrary to the above, as of June 19, 1989, procedures for safely opening packages in which licensed material is received were not followed. Specifically, packages containing licensed material that were received in Nuclear Medicine were not surveyed three feet from the package and at the surface of package prior to opening in accordance with licensee's established safe opening procedure.

This is a Severity Level IV violation. (Supplement IV)

C. Condition 23 of License No. 20-09568-17 requires that licensed material be possessed and use in accordance with statements, representations and procedures contained in an application dated January 13, 1984.

Item No. 10 of this application requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8, Revision 1.

1. Item E of Appendix D, Section 2, requires that the linearity of a dose calibrator be ascertained quarterly over the entire range of activities employed.

Contrary to the above, on March 29, 1988 and December 15, 1988, the linearity of the dose calibrator was not ascertained over the entire range of activities employed. Specifically, on March 29, 1988 the linearity of the dose calibrator was tested with a maximum activity of 122 millicuries and on May 18, 1988 150 millicuries of iodine-131 were assayed in the dose calibrator. In addition, on December 15, 1988, the linearity of dose calibrator was tested with a maximum activity of 635 microcuries and patient doses in the millicurie range were routinely assayed in the dose calibrator following the test.

2. Item B of Appendix D, Section 2, requires that the dose calibrator be tested for linearity and accuracy at the time of installation.

Contrary to the above, in May 1988, a replacement dose calibrator was not tested for linearity at the time of installation and the calibrator was used to assay patient doses until June 8, 1988.

These are Severity Level IV violations. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, The Children's Hospital - Boston is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

SEP 27 1989

Docket Nos. 030-08021
030-11864

License Nos. 20-09568-17
20-09568-18

The Children's Hospital - Boston
ATTN: Susan Pantaleoni
Office of Research Administration
300 Longwood Avenue
Boston, Massachusetts 02115

Gentlemen:

Subject: Inspection No. 030-08021/89-01

This refers to your letter dated August 31, 1989, in response to our letter dated August 8, 1989.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
Mohamed M. Shanbaky

Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts

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09/13/89

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The Children's Hospital • Boston

300 Longwood Avenue, Boston, Massachusetts 02115 • Telephone (617) 735-7048

Office of Research Administration

August 31, 1989

Mr. Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety and Safeguards
Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

REF: Docket Nos. 030-08021
030-11864
License Nos. 20-09568-17
20-09568-18

Dear Mr. Shanbaky:

I am responding to your letter of August 8, 1989 regarding Routine Inspection No. 89-001 conducted on June 19 and 20, 1989. As a result of that inspection, four severity level IV violations were identified which require a response as to the corrective action taken regarding the violations.

The first violation concerned a physician who administered 150 millicuries of I-131 in liquid form to a therapy patient and failed to have a thyroid bioassay. Since the administration took place on May 18, 1988, and the bioassay error was discovered June 19, 1989, and given the physical and effective half-life of I-131 being 8 days and 2-3 days respectively, and that the physician now practices in Florida, we felt it impractical for him to report for a thyroid bioassay at this point in time. Also, R. Amoling, Radiation Safety Officer, was with the physician when the therapy dose was administered and had a thyroid bioassay, with no measureable I-131 burden. We therefore conclude that the physician involved had no measureable thyroid burden and the concentration of I-131 in the air did not exceed the limits specified in 10 CFR Part 20. In order to prevent further violations of this nature, a log will be kept of all persons in the room at the time an I-131 therapy is being administered. Persons involved will be required to report for a scan the next day to determine thyroid burden as detailed in section 10, Appendix P, Regulatory Guide 10.8, Revision 2. We are now in

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compliance.

The second violation concerned packages containing licensed materials received in Nuclear Medicine which were not surveyed three feet from the package and at the surface of the package prior to opening in accordance with established safe opening procedures. In order to prevent further violations, the Radiation Safety Officer conducted a review of Nuclear Medicine safety with the staff. All Nuclear Medicine staff have been re-trained in the area of safe opening procedures of packages containing licensed material. We are now in compliance.

The third violation concerned the linearity of the dose calibrator which was not ascertained over the entire range of activities employed. We accept the finding that on March 29, 1988 the dose calibrator linearity was tested with a maximum activity of 122 millicuries and on May 18, 1988 150 millicuries of I-131 were assayed in the dose calibrator. In order to prevent further violations of this type, the dose calibrator will always be checked for linearity with activities over the entire range of activities employed. In addition, the inspectors reported that on December 15, 1988, the linearity of the dose calibrator was tested with 635 microcuries and patient doses in the millicurie range were assayed in the dose calibrator following the test. Subsequent review of our records show that on December 15, 1988 the dose calibrator was tested for linearity with 635 millicuries, thus we had in fact complied with the license condition. We are now in compliance.

The fourth violation concerned a replacement dose calibrator which was not tested for linearity at the time of installation in May 1988, and the calibrator was used until June 8, 1988. In order to prevent further violations of this nature, any replacement dose calibrator received by Nuclear Medicine will be checked for linearity before it is used to assay patient doses. Also, the Nuclear Medicine staff has been re-trained in the replacement dose calibrator linearity testing requirement. We are now in compliance.

In light of the corrective actions already taken by The Children's Hospital regarding violations identified during the inspection of June 19 and 20, 1989, I can assure you that we are in full compliance.

Sincerely,

Susan Z. Pantaleoni
Director for Research Administration

cc: S.T. Treves, M.D., Chairman, Radiation Safety Committee
Ronald Amoling, Radiation Safety Officer

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

DOCKET NUMBER: 30-08021

	REPORT NUMBER	STATUS	DATE OPEN	DATE CLOSED	REVIEWER NAME	CLOSING OPTION	REFER
1	87-001	CLOSED	08/06/87	06/20/89	DARDEN, TERESA	VIOL	89-001
	ITEM: FAILURE TO WEAR LAB COATS AS REQUIRED						
2	87-001	CLOSED	08/06/87	06/20/89	DARDEN, TERESA	VIOL	89-001
	ITEM: FAILURE TO CALIBRATE SURVEY METER AS REQUIRED.						
3	87-001	CLOSED	08/06/87	06/20/89	DARDEN, TERESA	VIOL	89-001
	ITEM: FAILURE TO PERFORM BIOASSAYS WITHIN THIRTY DAYS OF HANDLING IODINE AS REQUIRED.						
4	87-001	CLOSED	08/06/87	06/20/89	DARDEN, TERESA	VIOL	89-001
	ITEM: AUTHORIZED USER EXCEEDED POSSESSION LIMITS FOR PERMIT.						
5	89-001	CLOSED	06/20/89	09/17/90	MILLER&KIRKWOOD	VIOL	90-001
	ITEM: 20.201 FOR 20.103 PHYSICIAN ADMIN 150 MCI OF I131 IN LIQUID FORM, NO BIOASSAY						
6	89-001	CLOSED	06/20/89	09/17/90	MILLER&KIRKWOOD	VIOL	90-001
	ITEM: 20.205 FAILURE TO FOLLOW SAFE OPENING PROCEDURES SURVEYS AT 3 FT & SURFACE NOT PERFORMED						
7	89-001	CLOSED	06/20/89	09/17/90	MILLER&KIRKWOOD	VIOL	90-001
	ITEM: LINEARITY TEST NOT PERFORMED OVER FULL RANGE OF ACTIVITIES						
8	89-001	CLOSED	06/20/89	09/17/90	MILLER&KIRKWOOD	VIOL	90-001
	ITEM: LINEARITY TEST NOT PERFORMED ON "LOANER" DOSE CALIBRATOR AT TIME OF INSTALLATION						
9	89-168	CLOSED	11/12/89	09/17/90	ULLRICH	LER	90-001
	ITEM: THERAPEUTIC MISADMINISTRATION						
10	90-001	OPEN	09/17/90	/ /	ULLRICH	VIOL	
	ITEM: RECORDS OF WEEKLY SURVEYS IN HOT LAB NOT AVAILABLE 11/89; 3/15, 4/22, 4/27, 6/22, 6/29, AND 7/15/90.						

D/163