REGION I Form 198-C
(July 82)

MEDICAL

LICENSE NO: 20-12063-01

DOCKET NO. (s) 030-01945 File

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ATTACHED
- ☒ Appendix A
- ☒ Appendix B
- ☒ Appendix C
- ☐ Memo

INSPECTION REPORT NO. 030-01945/92-001

Mount Auburn Hospital
330 Mount Auburn Street
Cambridge, Massachusetts

LICENSEE CONTACT: Merrill Johnson, M.D (RSO) Telephone No: (617) 492-3500

LICENSE NO: 20-12063-01 CATEGORY G PRIORITY: 3

CATEGORY PRIORITY:

CATEGORY PRIORITY:

INSPECTION DATE (s): March 17, 1992 TYPE OF INSPECTION:
- ☐ SPECIAL
- ☒ ROUTINE
- ☒ DAYSHIFT
- ☐ OTHER
- ☐ ANNOUNCED
- ☒ UNANNOUNCED

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 BASIS IN APPENDIX C

- ☐ CHANGE CATEGORY TO:
- ☒ NEXT INSPECTION DATE: 04/91
- ☐ CHANGE PRIORITY TO:

PERSONS CONTACTED

* Dean DeMaster CNMT
Kathy Cardinale NMT
Deborah Merino NMT
Kathy Surles NMT
* Merrill Johnson M.D. RSO
Nancy Tarsa, Clinical Specialist
Marna Magri Senior Chemistry Tech
* Gerald Foley Admin
* Francis Lynch President

INSPECTOR: Susan Courtemanche 4/27/92

APPROVED: John F Glenn

* Present at Exit Interview

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INSPECTION PLAN AND REPORT NUMRER 030-01945/85-001 Page 2 of 10

Plan Approved: _____ Date: 4/14/88

Licensee: Mt Auburn Hospital License No. 20-12063-01

Inspection Items	Scheduled for Inspection	Post Inspection Status	Module No.
Management Meeting - Entrance and Exit Interviews (Required)			30703B
Program Requirements, MC 2860 (Required)			78710B
Followup on Noncompliance and Deviations			92702B
Independent Inspection Effort (Required)			92706B
Transportation			86740B

AREAS INSPECTED AND FINDINGS

Licensee: Mt Auburn Hospital License No: 20-12063-01

INSPECTION ITEMS	CRITERIA	FINDING

1. Organization Lic Cond ________ C

Structure of organization as described in requirements? Dean DeMaster (CNMT) reports any problems to Merrill Johnson MD (RSO) so that it may be reported to RSC.

Scope of Program? Patient load? 3500-4000 patients/yr (15/16 per day); M-F 7:00AM-5:00PM

NOTES & REMARKS: 3 full time techs + CNMT + 1 part time intern. Standard Medical imaging and labelling tests (infrequently seen) 800 Bone; 600 Stress, 400 Lung, 350 Thyroid Uptake 350 Misc out of 3500 (10-12 Thyroid uptake) cases

2. Licensee Internal Audits Lic Cond ________ NC

Scope and frequency of audits as required? N/C RSC met 4/85; 11/85; 5/86; 4/87; 10/87; 3/88 required frequency is quarterly.

Conducted by appropriate persons?

Records maintained? Records maintained of the meetings. They should cover more material than they have. RSO should be more involved in the program.

Reviewed by management?

Deficiencies identified and corrected? Deficiencies in RSC meeting frequency and who should attend was brought to their attention by consultant. Other problems brought up by Dean DeMaster.

NOTES & REMARKS:

3. Training and Qualification of Personnel Lic Cond ________ C

Training & retraining conducted as required? Training of nurses and techs conducted by consultant at required interval covering topics necessary for annual training. No tests.

Written & oral exams conducted?

Examination results reviewed by management?

Instructions to workers per 19.12? C 19.12

Authorized users? On license? Available in emergency? Lic Cond ________ Drs Chandler, Arons, Kettner and Johnson are associated with the hospital. Dr Nolan is no longer there. Drs Strauss, McKusick and Bannon are associated with Mass General.

NOTES & REMARKS: Has used visiting physicians to cover for emergency work during the weekends otherwise covered (See Item 15)

4. Radiation Protection Procedures Lic Cond ________ C

Procedures available and implemented? Identify radiopharmaceutical and dose(s)? Cover handling of patients receiving therapeutic doses? ~~Cover handling of cadavers?~~ Unit doses or labelling of syringe should used to identify radiopharmaceutical. Dose calibrator used to determine dose. Hyperthyroidism treated with I-123

Close out Surveys on Patients receiving temporary implants? N/A 35.14 (b)(5)(v)

Emergency procedures for spills, etc? Personnel understand procedures? Personnel appeared knowledgeable of what to do in case of spills and incidents.

NOTES & REMARKS:

AREAS INSPECTED AND FINDINGS

Licensee: Mt Auburn Hospital License No: 20-12663-01 Amendment No: 33

INSPECTION ITEM	CRITERIA	FINDING
5. Use of Materials		NC
Procurement and use as required? Authorized form & route of administration?	35.14(b)	Receives I-123 capsules from Mallinkrodt, unit doses and iodine rack from Syncor. Licensed material used for diagnostic tests and hyperthyroidism.
Special tests (moly breakthrough, leak tests, etc) required?	35.14(b)(4)	
Inventory of brachytherapy sources? NA	35.14(b)(5)	
Dose calibration checks performed?		I-131 has not been used since 1982. Use of Xe-133, Tc-99m and I-123.
Posting & labeling as required? C	20.203	Sealed sources were last leak tested 12/86, and 10/87.
NOTES & REMARKS: NC Moly dose calibrator checks not performed on days of emergency use or but/Sun. Quarterly annually performed C annual / annually Check C Geometry Checks performed C.		
6. Storage of Materials		C
Material secured in both restricted and unrestricted areas? Adequately?	20.207	Waste storage room is kept locked. Hot lab was open but personnel had it under surveillance.
NOTES & REMARKS:		
7. Facilities	Lic Cond	C
As described in lic cond or application? Any changes made? Adequacy?		No changes have been made in the facilities since the last amendment.
NOTES & REMARKS:		
8. Instruments	Lic Cond	C
Survey meters & instruments adequate for program? Instruments & meters operable? Calibrated? Calibration adequate?		Survey meters (2) were operable at time of inspection. Meters were calibrated at the required frequency.
NOTES & REMARKS:		

AREAS INSPECTED AND FINDINGS

Licensee: Mt Auburn Hospital   License No: 20-12063-01 Amendment No 33

INSPECTION ITEMS	CRITERIA	FINDING
9. Receipt and Transfer of Material		C
Written procedures for pickup, receiving, opening packages? C	20.205	Orders for material recorded and signed off on. Procedures for receiving after hours is followed
Survey of packages when received? C	20.205(c)(1)	
Records of survey of packages? C	20.401(b)	
Transfer of materials proper? Transfer records maintained? C	30.41, 30.51	RIA lab has standing orders for material kits used B-12 (~125 uCi/batch) TSH (~ uCi) T (~30 uCi) T3 (~24 uCi)
Authorized containers used? Shipping papers & package labels proper for packages on hand? C	71.5	

NOTES & REMARKS: Surveys of packages when they are received by nuc med are done by the techs and recorded. No transfers except used unit dose syringes

INSPECTION ITEMS	CRITERIA	FINDING
10. Personnel Protection - External		NC
Personnel monitoring controls adequate? Exposures minimized?	20.101, 20.202	Records show that badges are exchanged monthly. Those that are damaged or missing are assigned exposures. Appears adequate.
Exposure records (NRC-4 or 5) maintained? Available for employee review?	20.102(b), 20.401(a)	
Surveys conducted? Adequate?	20.201 NC	Daily surveys not done during weekends when emergency use is done. Recorded in normal use days.
Records of monitoring, surveys?	20.401	
Levels in unrestricted areas within limits? (Particularly around nuclear med. hot lab rooms of brachytherapy patients)	20.1, 20.105	

NOTES & REMARKS: Background

INSPECTION ITEMS	CRITERIA	FINDING
11. Personnel Protection - Internal		C
Airborne concentrations in restricted areas? (Xe-133, patients treated with I-131)	20.103	Airborne concentrations kept down because of Pulmonex. Assessed they air exchange not sufficient to clear air as per license
Exposures to minors? None	20.104	
Posting of airborne radioactivity areas? C	20.203(d)	No I-131 use.
Survey, monitoring bioassay adequate for airborne radioactivity, surface contamination? Records maintained?	20.201 20.401	Weekly surveys performed and recorded as required
Procedures for use of Xe-133 followed? C		

NOTES & REMARKS:

AREAS INSPECTED AND FINDINGS

Licensee: Mt Auburn Hospital License No: 20-12063-01 Amendment No: 33

INSPECTION ITEM	CRITERIA	FINDING
12. Effluent Controls, Waste Disposal		C
Release of effluents contolled? (particularly Xe-133, radioiodine where used) — Xe trapped in charcoal filter. Filter	20.106, 20.33	RIA lab maintains 4 55-gallon drums for waste and keeps them
Waste disposals controlled? — decayed when removed from system	20.301, 20.303, 20.304, 20.305	30 half-lives before surveying them prior to disposal
Procedures, records maintained?	20.401, Lic Cond ______	to normal waste stream
Surveys made? Adequate?	20.401	Nuc Med decays gloves and paper products 10 half lives. Records are in order. Unit dose syringes returned to manufacturer

NOTES & REMARKS:

Waste is separated as per the license 1) paper products, gloves to leaded trash bins 2) Empty vials kept segregated for decay. 3) Tc 99m, used syringes, Xe133 are in leaded containers.

INSPECTION ITEM	CRITERIA	FINDING
13. Notifications and Reports		C
To individuals? — C	19.13	
Overexposures, excessive levels & concentrations, incidents?	20.403, 20.405	None
Personnel exposures and monitoring, termination reports?	20.407, 20.408	Monitoring C Termination report on request
Theft or loss of licensed material?	20.402	None
Misadministrations?	35.41-35.45	MLER 87-037 reported

NOTES & REMARKS:

INSPECTION ITEM	CRITERIA	FINDING
14. Posting of Notices		C
Part 20, license & documents, procedures, notice of violations posted?	19.11(a)	Posted as required
NRC-3 posted?	19.11(c)	

NOTES & REMARKS:

15. Other License Conditions NC

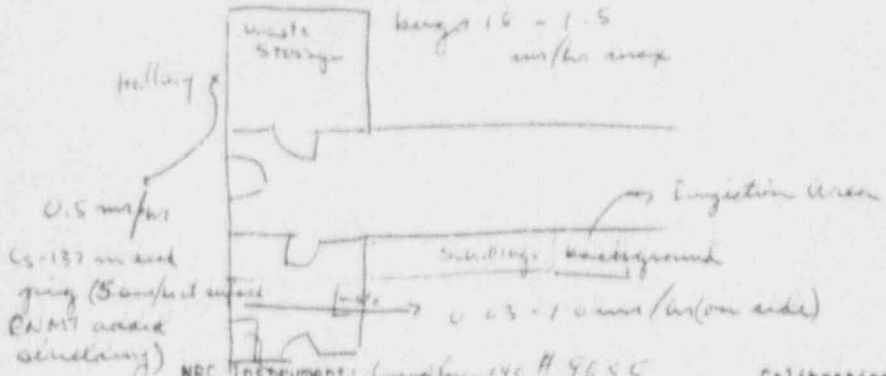
LC 15 Visiting physicians (not from Mass General) covering nuclear medicine scans without prior RSC approval (Admin approval, however) Aug 1, 1986, Sept 1, two instances.

AREAS INSPECTED AND FINDINGS

Licensee: Mt Auburn Hospital License No: 20-12663-01 Amendment No: 33

INSPECTION ITEMS	CRITERIA	FINDING

16. Confirmatory Measurements (C



NRC Instrument: Ludlum 14C # 9655 Calibration Due Date: 6/4/02

17. Independent Inspection Effort (PC, Gr Trans 15

Gloves, ring badges worn properly, lab coats, syringe shields used

Visiting physicians w/o RSC permission are

NC Dr. Hakan Arslan, Isabelle Rowsner of University Hospital of Boston
Dr Bernie Anderson St Elizabeth.

18. Incidents and Events (C

Any incidents of mis&dminstrations, contamination, etc., not otherwise covered by reports?	35.41 -35.45 20.402, 20.403, 20.405

None

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APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

Licensee: Mount Auburn Hospital License No: 20-12643-01

Reference	Basis for noncompliance
Report item 15 10 CFR Lic Cond 15 Type n/c IV	Visiting physicians did work involving nuclear medicine during weekends w/o RSC written approval.
Report item 5 10 CFR 35.50 Lic Cond Type n/c IV	Daily dose calibrator constancy checks not performed on days of emergency use on weekends.
Report item 10 10 CFR 20.201 Lic Cond Type n/c IV	Daily surveys not performed on nuclear medicine during days of emergency use on weekends
Report item 2 10 CFR 35.22 Lic Cond Type n/c IV	RSC did not meet at the required quarterly interval.
Report item 5 10 CFR 35.59 Lic Cond Type n/c IV	Sealed sources for calibration of dose calibrator were not leak tested at the required six month frequency.
Report item 10 CFR Lic Cond Type n/c	

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APPENDIX B - LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS

Licensee: Mt. Auburn Hospital License No: 20-12563-01

Identification and summary of action taken	Status
Report No: MLEIR-87-031 Type n/c: Diagnostic Nuc Administration Describe: Syringe put on incorrect radiopharmaceutical on unit dose Action taken: No recurrence Reported. Syringe was labelled Osteolite instead of Ni pentahydrate	OPEN CLOSED
Report No: 030-01945/85001 Type n/c: III Describe: Opening package survey not conducted Action taken: Opening package survey conducted on days packages were received.	OPEN CLOSED
Report No: 030-01945/85001 Type n/c: III Describe: No daily survey once Action taken: Survey meters available. (1) Daily surveys performed on weekdays but not on days of emergency use. (Sat/Sun)	OPEN CLOSED
Report No: 030-01945/85001 Type n/c: IV Describe: No weekly survey performed Action taken: Weekly wipe surveys performed	OPEN CLOSED
Report No: 03-01945/85001 Type n/c: IV Describe: No surveys of packages returned to NRC Action taken: When applicable, packages are surveyed prior to return to the manufacturer.	OPEN CLOSED
Report No: Type n/c: Describe Action taken:	OPEN CLOSED

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APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: Mt Auburn Hospital License No: 20-12063-01

( ) Uncorrected/repeated noncompliance ( ) Unresolved items
( ) Unusual occurrence, conditions, etc (X) Inspector's comments
( ) Basis for change of Category or Priority

Most of the program is run by the CNMT (Asst "Rad Master) There are 3 full-time technicians and one part-time student besides the CNMT. Nuclear Medicine is open from 7:00AM - 5:00PM but the NMT's are on 24 hour on-call service. There has been work during the weekends with none of the tech's or Doctors from ~~from~~ assure the proper operation of the instruments. Doctors from the hospitals cover for the hospital in order to read scans they are authorized for the studies but no documentation of their approval was in the minutes of the RSC.

13-14 scans are performed every day (~3800 - 4000 patients yearly making it a mid-size to large program)

A breakdown of the studies:

- 800 Bone scans
- 600 Stress tests
- 400 Lung scans
- 350 Thyroid uptake
- 350 ? Miscellaneous
- 10-12 Hyperthyroid therapy but no ablations

Tries to always use unit doses. Keeps unit task on hand in case of a "rush job" (Surgeon)

Mallinkrodt supplies the I-123 capsules.

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

DOCKET NUMBER: 30-01945 LN: 20.12063-C/

	REPORT NUMBER	STATUS	DATE OPEN	DATE CLOSED	REVIEWER NAME	OPTION	CLOSING REFER
1	87-039	CLOSED	01/19/87	04/14/88	DICK LADUN	LER	88-001
	ITEM: DIAGNOSTIC MISADMINISTRATION						
2	85-001	CLOSED	06/13/85	04/14/88	JOHANSEN	VIOL	88-001
	ITEM: NO OPENING PACKAGE SURVEYS ON JUNE 3, 4, 9, 10, 12 1985.						
3	85-001	OPEN	06/13/85	/ /	JOHANSEN	VIOL	-
	ITEM: NO DAILY SURVEYS SINCE 5/29/85						
4	85-001	CLOSED	06/13/85	04/14/88	JOHANSEN	VIOL	88-001
	ITEM: NO WEEKLY WIPE SURVEY SINCE 5/30/85.						
5	85-001	CLOSED	06/13/85	04/14/88	JOHANSEN	VIOL	88-001
	ITEM: NO SWIPES OF RETURNED LICENSED MATERIAL TO NPI.						
6	88-001	OPEN	04/14/88	/ /	COURTEMANCHE	VIOL	-
	ITEM: VISITING PHYS. DID WORK COVERING FOR THE HUSPITAL DURING THE WEEKENDS W/O RSC WRITTEN APPROVAL.						
7	88-001	OPEN	04/14/88	/ /	COURTEMANCHE	VIOL	-
	ITEM: CALIBRATOR DAILY CHECKS NOT PERFORMED ON WEEKENDS WHEN THERE IS EMERGENCY WORK.						
8	88-001	OPEN	04/14/88	/ /	COURTEMANCHE	VIOL	-
	ITEM: DAILY SURVEY OF NUCLEAR MEDICINE NOT PERFORMED ON DAYS OF EMERGENCY WORK DURING THE WEEKENDS.						
9	88-001	OPEN	04/14/88	/ /	COURTEMANCHE	VIOL	-
	ITEM: RADIATION SAFETY COMMITTEE DID NOT MEET AT THE REQUIRED QUARTERLY FREQUENCY.						
10	88-001	OPEN	04/14/88	/ /	COURTEMANCHE	VIOL	-
	ITEM: LEAK TESTS OF THE SEALED CALIBRATION SOURCES WERE NOT PERFORMED AT THE REQUIRED SIX MONTH INTERVALS.						