Salem Hospital

81 Highland Avenue Salem, Massachusetts 01970 Telephone (617) 741-1200

October 12, 1988

John E. Glenn, Ph.D., Chief Nuclear Materials Safety Section A Division of Radiation Safety and Safeguards Nuclear Regulatory Commission Region 1 475 Allendale Road King of Prussia, Pennsylvania 19406

Dear Mr. Glenn:

Please find enclosed Salem Hospital's response to violations cited during a routine inspection conducted by Mr. John M. Pelchat on July 6, 1988; Inspection #88-001, Docket #030-01803.

If additional information is required, please contact Mr. Anthony Mazzola, Radiation Safety Officer, Salem Hospital.

Sincerely,

Duny (Michael J. Geaney

Michael J. Gean President

WTD: jlg

cc: Mr. Anthony Mazzola, Radiation Safety Officer

Salem Hospital Salem, MA 01970 License #20-00083-02 Docket #030-01803

Item A.

1. Corrective Action Taken to Achieve Compliance

a) All stated violations from August 7, 1987 through May 8, 1988 were traced to <u>one staff technologist</u>, by our weekend and night call logs. These logs were shown to Mr. Pelchat. This staff technologist (with 17 years experience in the field) is no longer employed at Salem Hospital. All other staff technologists have complied with set forth regulations. A staff meeting was held to review the inspection (see Attachment 1).

2. Corrective Steps Taken to Avoid Further Violation

a) The Nuclear Medicine Computer (Dupont Nuclear Medicine Manager) has been installed. The system has been designed such that when technologists enter the patient's information (demographics, type of study, date and time performed) there are built-in safeguards which will not allow you to proceed with the testing until the moly assays have been performed, and the numerical values have been entered into the system.

The moly assays will now be performed on a daily basis regardless of whether or not the agent is used that day. These will also be logged on the Hot Lab Daily Sheet on a daily basis and reviewed by the Manager of Nuclear Medicine (see Attachment 2).

3. Date of Compliance: September 1, 1988.

Item B1&2.

- 1. Corrective Action Taken to Achieve Compliance
 - a) On July 7, 1988 a critique of Mr. Pelchat's inspection was reviewed with the staff technologists, students and secretary. The staff technologists were told again, that millicurie doses of Iodine-131 after surveys and wipe tests, must be opened in the fume hood. Further, if multiple draws from the same vial are required, each time the vial is opened, it must be opened in the fume hood.
 - b) Only the Manager of Nuclear Medicine and the Senior Technologist may prepare therapeutic doses. When the dose is prepared, it must be logged in the Hot Lab Daily Sheet under other agents. The amount, time, date, and technologist's initials must be entered (see Attachment 2).
 - c) When millicurie amounts of Iodine are entered into the computer, it automatically generates fault flags. Fume Hood Surveys must be performed, therefore alerting staff that radiopharmaceuticals must be opened in a Fume Hood.

- d) The "End of Day" Reports from the computer cannot be generated until Fume Hood Wipes and Thyroid Bioassays are completed and the print outs are generated.
- 2. Corrective Steps Taken to Avoid Further Violations
 - a) Ongoing in-service education to make staff aware of regulations as well as condition of license.
 - b) Limiting number of staff involved in millicurie doses of Iodine.
 - c) Computer fault flags which will require regulatory compliance especially in regards to thyroid bioassays (see Attachment 3).
 - d) Performing thyroid bioassays on the same day.
 - e) Review of dose preparations, fume wipes and thyroid bioassays, by the Radiation Safety Officer or his designate within 24 hours.
 - f) In the event of computer failure, refer to the manual calculation form to achieve compliance (see Attachment 3A).
- 3. Date of Compliance: September 1, 1988.

Item B3.

- 1. Corrective Action Taken to Achieve Compliance
 - As shown to Mr. Pelchat, the constancy tests that were not performed were attributed to one staff technologist who is no longer employed at Salem Hospital.
 - b) There are 3 checks that constancy testing has been performed:
 - 1) Daily Hot Lab Sheet (Attachment 2);
 - 2) Daily Constancy (Attachment 4);
 - 3) Instrument Constancy Dose Calibrator Computer (Attachment 5).
 - c) Prior to any input in the computer, constancy studies must be entered. For example, the Generator Elution, moly assays, alumina assays, etc. will not be accepted unless the constancy studies have been entered.
- 2. Corrective Steps Taken to Avoid Further Violation
 - a) Main source of v'olations no longer present.
 - b) Triple check system as outlined above.
 - c) Inability to use the computer until constancy figures are entered and initialed.
 - d) Daily review by Chief Technologist.
 - e) Constant in-service to insure integrity of regulations.
- 3. Date of Compliance: September 1, 1988.

Item B4.

- 1. Corrective Action Taken to Achieve Compliance
 - a) A journal has been posted with required dates for testing (Attachment 6).
 - b) The computer generates a seven day pre-notification "flag" to afford compliance in a timely manner. However, if proper time sequence is <u>NOT</u> followed, Fault Flags will not allow further entry of ANY QC Data.

- 2. Corrective Steps Taken to Avoid Further Violations
 - a) Staff Technologies were been assigned to perform studies and insure their base of the studies were performed on paper but not posted.
 - b) Linearity tests have been entered into the computer for further inspections.
 - c) Ongoing in-service.
- 3. Date of Compliance: September 1, 1988.

Item B5.

- 1. Corrective Action Taken to Achieve Compliance
 - a) The accuracy tescs were performed as were the linearity tests on November 17, 1987, and February 24, 1988, as part of our Student Training Program. However, the results were not posted. Staff technologists have been assigned this responsibility. Assigned dates have been posted, as well as computer generated reports with flags indicating a seven day notice for the test to be performed.
 - b) In-service education to impress on the staff the serious nature of noncompliance.
- 2. Corrective Steps Taken to Avoid Further Violations
 - a) Assigned duties to the staff.
 - b) Posting dates of testing to assure timely compliance.
 - c) Computerizing Testing Results.
 - d) In-service.
- 3. Date of Compliance: September 1, 1988.

Note: Date of Compliance of September 1, 1988 is when all data entries were in the computer. We have had meetings and in-service after our critique with Mr. John M. Pelchat from the Commission. All the suggestions he made during his visit have been implemented.

Salem Hospital

81 Highland Avenue Salem, Massachusetts 01970 Telephone (617) 741-1200

Minutes Nuclear Medicine Stuff Meeting Subjects: NRC Inspection - Policy Changes

Date: July 7, 1988 Time: 3 pm

Present: M. Barker, J, Lipinsk', S. Spencer, R. Desjardins, L. Ellis Students: J. Vallie, U. Corbett, L. Gilbert

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- A. Review of the Inspection conducted by Mr. Pelchat of the NRC. Items of noncompliance were covered in depth, as well as new policy changes.
 - Moly Assays were not always performed when generator was eluted. This infraction occured during emergency off hours and weekends. Immediate corrective actions were discussed. These included new Nuclear Medicine Manager (computer) entries, hot lab daily log sheet, and hospital daily activity journal (DAJ) which gives date, time and hour patient study was performed. Mr. Mazzola will check these daily.
 - 2. A millicurie dose of Indine-131 was not opened in the Fume Nood, as well as thyroid bio assays not being performed in a timely manner. Conditions of our license were reviewed in regards to thyroid therapy, opening of millicurie vials in the fume hood, noting millicurie doses of Iodine on the hot lab daily log sheet, preparation of 5 mCi doses for thyroid uptakes and thyroid bio-assays. The procedure for performing bio-assay was reviewed. Further, the 24 hour time limit for thyroid bio-assays was revised to same day assays.
 - 3. Peview of dose calibrator constance testing was discussed. Policy change to include constancy testing daily. Along with normal QC testing weekends, constancy tests have been added. Entries such as hot lab daily log sheets, daily channel sheets and computer entries were formed as policy.
 - 4. A comprehensive review of Instrument Quality Control, documentation and posting were discussed. It was scressed that performing QC studies alone is not proof of compliance. The QC studies performed have to be logged and posted. A computer printout will be generated the first of each month. This printout will give details of all required instrument testing along with a 7 day notice for testing. Mr. Lipinski along with Mr. Mazzola will be responsible for assuring compliance.

5. Mr. Mazzola summed up the meeting with a detailed description of policy changes and procedures to be implemented when the Nuclear Medicine Computer software arrives, along with inservice. The meeting was adjourned at 4:30 pm.

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HOT LAB DAILY LOC

Attachment 2

 (Utilizing the Capintec Radioisotope Dose Calibrator) Identification Number: CRC-30 BC

WEEK OF

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
DATE	1.115-3						
TIME							
CALIBRATION							
6/2/87 Co57(5.8mCi) 3/13/87				-			-
Cs137(.211mCi) 2/21/87							
RADIOPHARMACEUTIC	ALS PREPARA	TION:					
99mTc Eluate/ml			_				
Moly/ml							
Alumina(10ug/ml)					_	_	
BONE AGENT/m1 _							
LIVER AGENT							
LUNG AGENT/m1		_					
HIDA AGENT/m1							
DTPA AGENT/m1							
HSA AGENT/ml							
THER AGENTS							
OTHER AGENTS /ml NAME							
REVIEWED BY MANACI	ER						

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at	e: :9/28/88		Sagtornar))) Thyroid bioassa	in the I-13			CALCULATION OF		
	SRLEM HOSPITRL - MAL									
	Name & Social Security Number	Test Date Next Due	Std Srce Pres.Act	Standard Source # Peak,Window Settings	StdNetCpm Ins: Eff.	Counting Instrument @ Peak,Window Settings	THY Thyroid BKG Cpm	Thyroid Activity		
	x4010.4 861406 L. 859-011-29-2971	03/28/88 10/28/88	0.333663 (vCt)	Siel-131 Roo Source Serial #000033 300/100 364	14641 1.99%	Thyroid Uptake System Serial #210184035 1-131: 300/100 364	110 Total: 15	9 08) (20)		

All results were below the investigation level of 0.040 uCi No corrective action is necessary.

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))) Thyroid bioassay "or I-131 (((

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SALEM HOSPITAL - MAI

))) Procedure (((

Thyroid bioassay for I-131 is required at this facility according to -Applicable conditions of the facility Radioactive Materials License and government regulations. Please refer to the facility bioassay

Instrument Standard ...et Com Standard Com - Background Com Efficiency = ----- = Efficiency in Cpm/Dpm Standard Dpm Std Activity x 2200000 Dpm/uCi (Eff x 100 = x)

Estimation of I-131 Well efficiency by calibration procedure setup. Correction is or Photon abundance difference Ba-133 * 62% I-131 * 82% i.e. Ba-133 Well efficiency * ratio I-131/Ba133 = I-131 Est Eff. Or the well has been calibrated for 1-131 Efficiency with an I-131 standard and the ratio is assumed to be relatively constant with respect to that of Ba-133 over a +/-5% relevant range

Statistical test # P = 0.01 , 1=2.33

____ 1/2 Tbkg [] Z 1 Rbkg I Detection Limit = ---- + 22 i ---- ; ; + ----- | 1 = Net Sample Cpw!! required to indicate Tsto I This : Istd 1 ! that activity was detected @ p=0.01

Thyroid Thy Cpe Net Thy Com Net Activity # -----

----- = Amount I-131 uC: Thyroid burden Std Cpm/uCi Effic Cpm/Dpm x 2200000 Dom/uCi

n 2	Performed by: MILTRU MANNA	L Title: Auditk
		T morent
- 8	Radiation Safety Officers	AN

))))) Dose	Calibrator Constancy		Attachment #
• Disse C	ION NEARE: SALEM H alibrator: CAPINT Isotope: Co-57 Mfg: DUFONI Serial#: S20660 CalDate: 03/13/ Nom.Act: 5.40	0SPITAL EC CRE 30BC 8-37 87 • #Ci	Serial Num Serial Serial Num Fig: DUPONT DD Serialt: \$356002-02 CalDate: 02/21/87 Nom.Act: 211.00 uCi	ber: 30675 Isotopw: Co-E0 Mfg: SUCONT DD Serial@: SN023006- CalDate: 06/02/87 Now.Act: 198.00 gC	01
• Date	-5% Eurnt Non.Act	+5% READING	-5× Current +5× Nom, Act	READING -5% Currnt +5% uCi Nou. Act	REALING
11-01/8	1.11 1.17	1.23	192.80 202.94 213,09	1 156.10 164.37 172.5	3 1 1
11/02/8	1.11 1.16	1.22	192. 78 202. 93 213. 08	1 156.04 164.25 172.4	7
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11/04/8	1.10 1.16	1.22	192.76 202.91 213.05	1 155, 93 164, 13 172, 3	41
1/05/8	1.10 1.16	1.21	192: 75 202. 89 213.04	1 155.87 164.08 172.2	8 1 1
11/06/8	1.09 1.15	1.21	192.74 202.68 213.02	1 155.82 164.02 172.2	
11/07/8	1.09 1.15	1.21	192.72 202.87 213.01	1 155.76 163.96 172.10	61
11/09/8	1.09 1.15	1.20	192.71 202.65 213.00	1 155.70 163.90 172.0	9
11/09/8	1.09 1.14	1.20	192.70 202.84 212.98	1 155.65 163.84 172.0	3
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Attachment #6

Page No. 1 Listing Of Calendar File For Services Due Or Due Within 30 Days

10/05/88

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Listing Of The Calendar File

** MA1 SALEM HOSPITAL 81 HIGHLAND AVENUE Due Date Of Change Of Film Badges-Film Badges..... 10/24/88 Due Every 30 Days Due Every 7 Days Due Date Of Channel Check-Dose Calibrator 10/06/88 Due Every 1 Days Due Date Of Area Surveys-Survey Meter..... 10/06/88 Due Every 1 Days Due Date Of Radiation Safety Meeting-Lab Rad-Safety 10/06/88 Due Every 30 Days Due Date Of Instrument Constancy-Dose Calibrator 10/06/88 Due Every 1 Days Due Date Of 1-131 Personnel Bicassay-MCA - Scaler..... 11/04/88 Due Every 30 Days Due Date Of I-131 Air Effluent Monitoring-Fume Hood 10/21/88 Due Every 30 Days Due Date Of Area Wipe Test-MCA - Scaler...... 10/06/88 Due Every 7 Days Due Date Of I-125 Personnel Bioassay-MCA - Scaler..... THIS SERVICE IS OFF

Due Date Of Radiation Safety Committee-Lab Management.... 10/06/88 Due Every 30 Days