

November 24, 1989

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

Docket Nos. 030-01867
030-00239
030-08948
030-15211

Dear Mr. Shanbaky:

I am writing in response to your report of inspection No. 89-001 which was conducted by Mr. John Pelchat on July 25-28, 1989.

A.1

10 CFR 19.12 During the course of his inspection, Mr. Pelchat conducted interviews with many persons he found in laboratories or laboratory areas posted as containing radioactive materials. During these interviews, Mr. Pelchat identified one individual who was a registered radiation worker with adequate formal training in radiation safety matters, yet who had frequented laboratory prior to attending the required weekly orientation program. The permit holder responsible for this worker has been identified and re-instructed to send all persons frequenting the laboratory for any reason to the weekly orientation program.

In general, the requirements of this section are met through policies identified in Item 12 Personnel Training Program of the license application and page 29 Section J. Training of Personnel in the MGH Radiation Safety Manual as follows:

"Regulations indicate that no person may work with radioactive materials without having attended a course. (Orientation) lectures are given on an informal basis of 1-2 hours which do not replace the structured (6 hour) course but enable an individual to work in a supervised environment until the course can be completed."

"All employees must attend a short orientation course in safe handling methods at the start of work."

A one hour formal orientation program is presented by the MGH Radiation Safety Program every Wednesday at 4:00 PM. All new employees and employees beginning work as registered radiation workers must attend this program during the first week of employment and prior to working in the laboratory or other controlled area. During the annual permit audit, each permit holder is requested to identify all radiation workers to ensure that they are registered with the MGH Radiation Safety Program.

A.2

10 CFR 19.12 All student teletherapy technologists will attend the MGH Radiation Safety Program weekly orientation program in addition to the orientation from the members of the Department of Radiation Medicine. The Radiation Safety Officer will examine the records of all such training during the annual audit of the Human Uses Permit under which such students work. (See Attachment #1)

B.1

10 CFR 20.201(b) Item 19 Therapeutic Use of Radiopharmaceuticals requires that a physicist survey the patient with an ionization chamber and complete the appropriate lines of the door tag and medical record label.

During 1988 there was 80 brachytherapy treatments conducted using Ir-192 or CS-137 and 21 brachytherapy treatments from January to July of 1989. While there were no written records located on 9 brachytherapy treatments in 1989, it is our belief that such surveys were conducted by Mr. Robert Beh, Assistant Radiation Safety Officer. Mr. Beh died tragically in September 1989 and was too ill during July and August to verify this belief.

Since August 1, the primary responsibility for conducting such surveys and maintaining records of such surveys has been delegated to the Radiation Medicine Department. The Radiation Safety Program provides supplemental monitoring to confirm their information and maintain a parallel record of treatment procedures. (See Attachment #1)

C.

- 1 During 1988 and 1989 , the MGH Radiation Safety Program has records that 27 iodine-131 treatments wre conducted by the staff and that the appropriate measurements were made prior to release of the patient from the hospital. The policy of the program is to not remove the sign from the door until the room is properly decontaminated and released for general use. However, there has been no written record to indicate the levels of contamination prior to decontamination and after. Such a record form has been developed, is enclosed and has been in use since November, 1989. (See Attachment #3)

- 2a It is standard practice for the responsibility to conduct routine daily and weekly surveys to revert to the Department of Nuclear Medicine if the Radiation Safety staff for whatever reason cannot meet the survey frequency requirement. During the periods in question, there were illness and reduced staff situation that required that Nuclear Medicine perform these surveys. It is our belief that the surveys were in fact conducted as per Attachment #4 yet these records were misplaced during transfer between the two groups. To prevent this from happening in the future, the health physics technologist will be responsible for collecting such records immediately upon return to work.

- 2b The policy to measure and make records of measurements of all areas of Nuclear Medicine which might become contaminated during weekend operations was implemented on July 29, 1989. The on-call nuclear medicine technologist is responsible for conducting such measurements and the records are checked on Monday mornings by the health physics technologist from the MGH Radiation Safety Program. An annual review of the Human Uses Permit issued to the Department of Nuclear Medicine will include a review of all records required to be kept by the Radiation Safety Program.

- 2c The Radiation Safety Office is responsible for conducting all daily and weekly surveys of the Nuclear Medicine Pharmacy work area and Administrative Areas. The Office will continue to meet this responsibility.

D.

According to license condition No, 20 of License 20-03814-14, item 17, the following corrections to previous operational policy have been made. (See Attachment #1)

- 1 The Radiation Medicine technologist on-call during weekends will perform the daily operational and safety checks prior to providing treatment during the weekend.

- 2 Records of these checks will be reviewed periodically by the teletherapy physicist and during the annual human uses permit application review by the Radiation Safety Officer.

Sincerely,

Stephen R. Larson M.S. CSP, CIH
Director of Safety



MASSACHUSETTS GENERAL HOSPITAL

HARVARD MEDICAL SCHOOL

DEPARTMENT OF RADIATION MEDICINE

Please reply to:
Massachusetts General HospitalBoston, Massachusetts 02114
Telephone (617) 726- _____
Telex: (617) 726-3603

MEMORANDUM

TO Maryanne Spicer
 FROM Edward Epp *ERE*
 DATE 11-22-89
 TOPIC NRC Notice of Violation

With regard to the violation of 10 CFR 19.12, the following steps have been taken:

1. Student teletherapy technologists will attend the Massachusetts General Hospital radiation safety orientation, provided by the Radiation Safety Office.
2. Student teletherapy technologists will receive orientation from a member of the radiation medicine staff regarding the applicable provisions of the NRC's regulations and licenses.
3. No student teletherapy technologist will be allowed to train on a teletherapy unit before the above orientation has been attended.

With regard to the violation of Condition No. 20, Radioactive Materials License No. 20-03814-14 the following provisions have been made:

1. The technologist on weekend call will perform the daily operational and safety checks before treating any patient over the weekend period.
2. Records of the operational and safety checks will be reviewed periodically by the designated teletherapy physicist.

Full compliance with the above responses will be achieved by December 1, 1989.

cc: K. McCarthy
 T. Mauceri
 J. Leong
 S. Larsen

MASSACHUSETTS GENERAL HOSPITAL



HARVARD MEDICAL SCHOOL

DEPARTMENT OF RADIOLOGY

Division of Nuclear Medicine



Mailing Address:

Massachusetts General Hospital
Boston, Massachusetts 02114
(617) 726-8350

November 24, 1989

Ms. Maryanne Spicer
Administrative Director of Safety
and Regulatory Affairs
Blossom Court

Dear Maryanne:

This letter constitutes our response to Notice of Violations found during the NRC inspection of Nuclear Medicine July 25-28, 1989. Specifically we are responding to item C.2, Appendix I, of NRC letter to you dated October 27, 1989.

The violation deals with the daily performance of radiation surveys in areas where radiopharmaceuticals are handled and weekly surveys of the waste storage areas.

The three areas of non-compliance found and are response to each are as follows:

- 1. No surveys of radiopharmaceutical handling areas were performed for 11 consecutive days in March 1989 and on 17 consecutive days in May 1989.**

Response: During the periods in question, the responsibility for daily surveys in Nuclear Medicine were being transferred between Radiation Safety and Nuclear Medicine due to personnel shortages in Radiation Safety. Mr. John Hergenrother, Area Manager in Nuclear Medicine states that the surveys were indeed performed during the periods in question. When Radiation Safety personnel again resumed responsibility for these surveys, our records were transferred to them. We unfortunately did not retain copies of these records in Nuclear Medicine and Radiation Safety cannot locate these records.

It is our position that this violation is a result of misplaced records and not as the result of failure to perform required surveys.

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November 24, 1989

- 2. No surveys of radiopharmaceutical handling areas were performed on weekends when nuclear medicine procedures were performed on-call.**

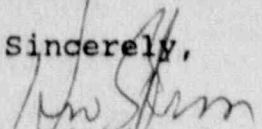
Response: No such surveys were carried out. This deficiency has been corrected effective July 29, 1989. A copy of the forms used by technologists when they are called in on weekends is enclosed for your review. (ATTACHMENT #4)

- 3. Weekly radiation surveys of Nuclear Medicine and radioactive storage areas were not performed during 13 weeks in 1988 and 13 of 29 weeks in 1989.**

Response: Weekly surveys and wipe tests of radiopharmaceutical handling areas and waste storage areas are the responsibility of the Radiation Safety Office. Nuclear Medicine personnel have never been informed that this responsibility was transferred to them, either temporarily or permanently. It is our understanding that this policy remains in effect.

Thank you for providing us the opportunity to respond to these violations. If you require additional information, please contact me.

Sincerely,


H. William Strauss, M.D.
Director, Nuclear Medicine Division
Radiologist, Massachusetts General Hospital
Professor, Harvard Medical School

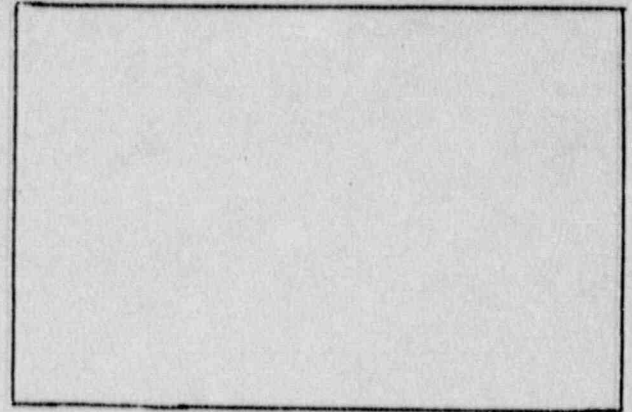
HWS/elp

cc: Ronald J. Callahan, Ph.D.
John Hergenrother, CNMT

V. SURVEY OF HOSPITAL ROOM AFTER PATIENT LEAVES

Sample floor plan

Date _____
 Survey Instrument _____
 Room _____
 Surveyed by _____

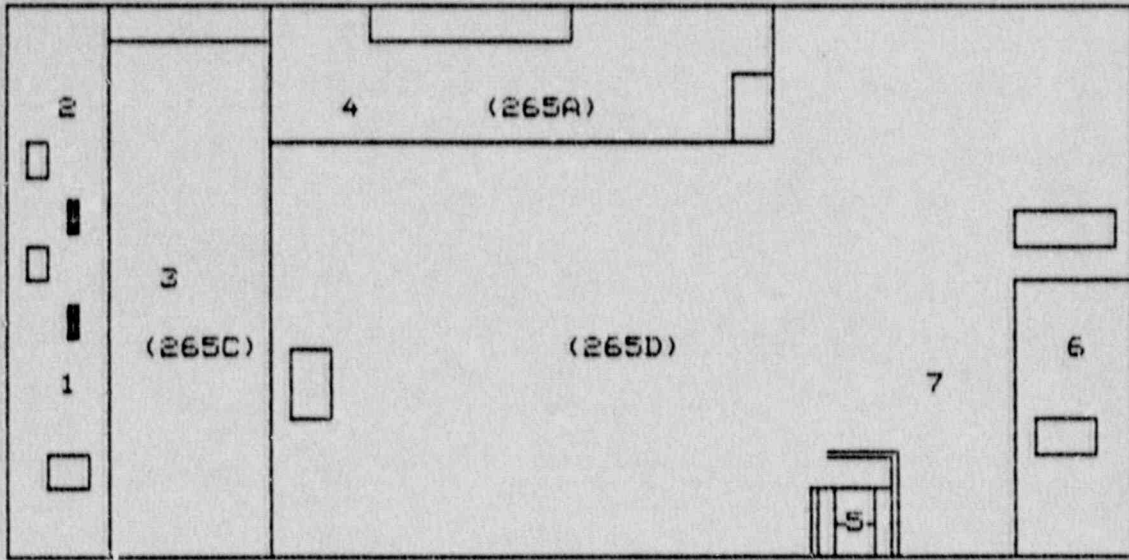


SURFACE SURVEY RESULTS (mR/hr)

<u>Key #</u>	<u>Place</u>	<u>Initial</u>	<u>After Cleaning</u>	<u>Final</u>
Main Room				
1	Floor-plastic			
2	Floor	---		
3	Bed			
4	Bed linen			
5	Pillow 1			
6	Pillow 2			
7	Over Bed Table			
8	Night Stand			
9	TV Control			
10	Bed Control			
11	Phone			
12	Chair			
13	Trash			
14	Bed Pans			
Bathroom				
15	Floor-plastic			
16	Floor	---		
17	Toilet Seat			
18	Toilet			
19	Sink			
20	Sink Fixture			
Extra Items				
21				
22				

Comments:

DISPENSING ROOM AND AREA
WHITE (265A, C AND D)



LOCATIONS

DPM/100cm²

1) BENCH	-----
2) BEN	-----
3) FLOOR	-----
4) FLOOR	-----
5) CHAIR	-----
6) BENCH	-----
7) FLOOR	-----

TRIGGER
LEVELS

2000
DPM/100cm²

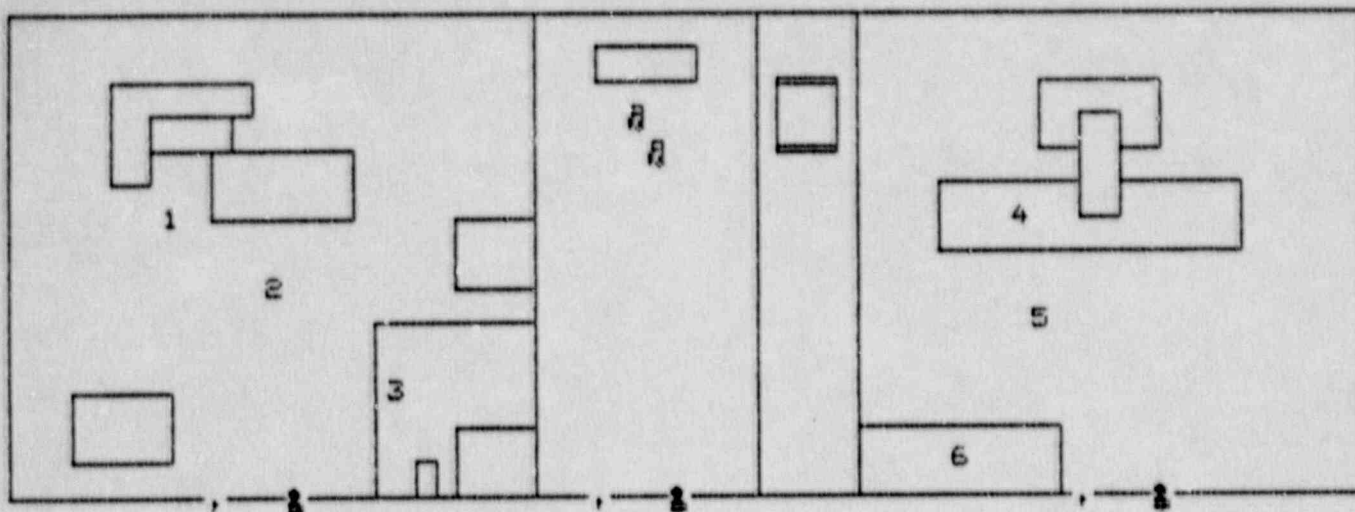
REMARKS:

DATE: -----
TIME: -----
METER: -----
INITIAL: -----

SCANNING ROOM 1 & 2

1 WHITE (281)

WHITE (283) 2



LOCATION

DPM/100cm²

1. TABLE

2. FLOOR

3. BENCH

4. TABLE

5. FLOOR

6. BENCH

TRIGGER
LEVEL

2000
DPM/100cm²

DATE: -----

TIME: -----

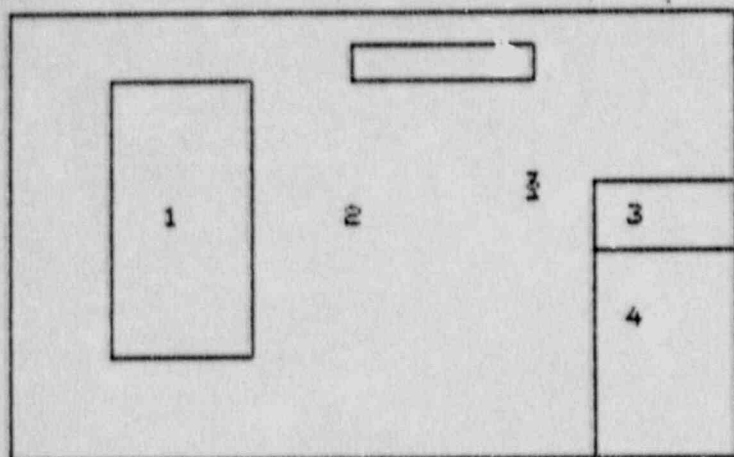
INITIAL: -----

METER: -----

REMARKS:

Empty box for remarks.

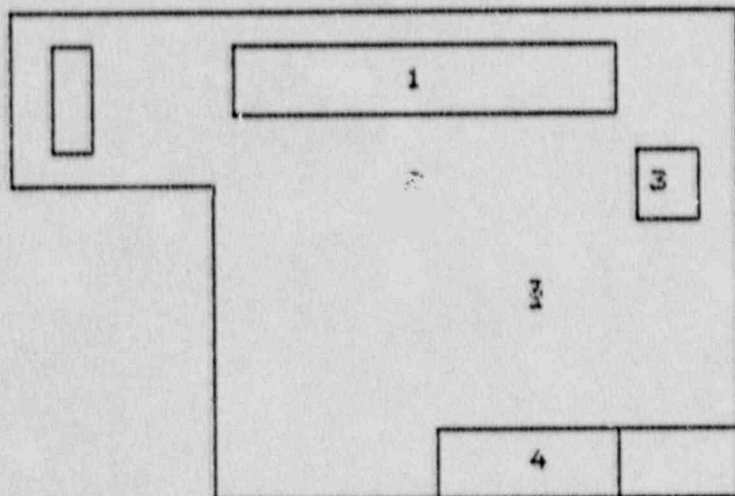
GEMINI 1
WHITE (240)



TRIGGER
LEVEL
2000
DPM/100cm²

LOCATION	DPM/100cm ²
1) TABLE	-----
2) FLOOR	-----
3) SINK	-----
4) BENCH	-----

GEMINI 2
WHITE (256)



LOCATION	DPM/100cm ²
1) TABLE	-----
2) FLOOR	-----
3) XENON	-----
4) SINK	-----

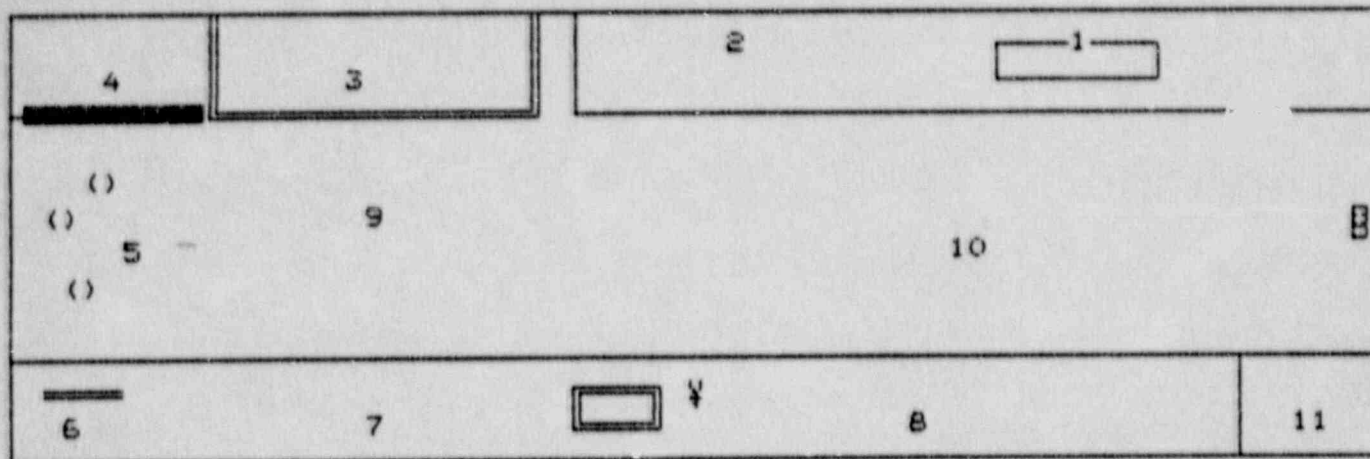
DATE: -----

TIME: -----

INITIALS: -----

REMARKS

RADIOPHARMACY
WHITE (258)



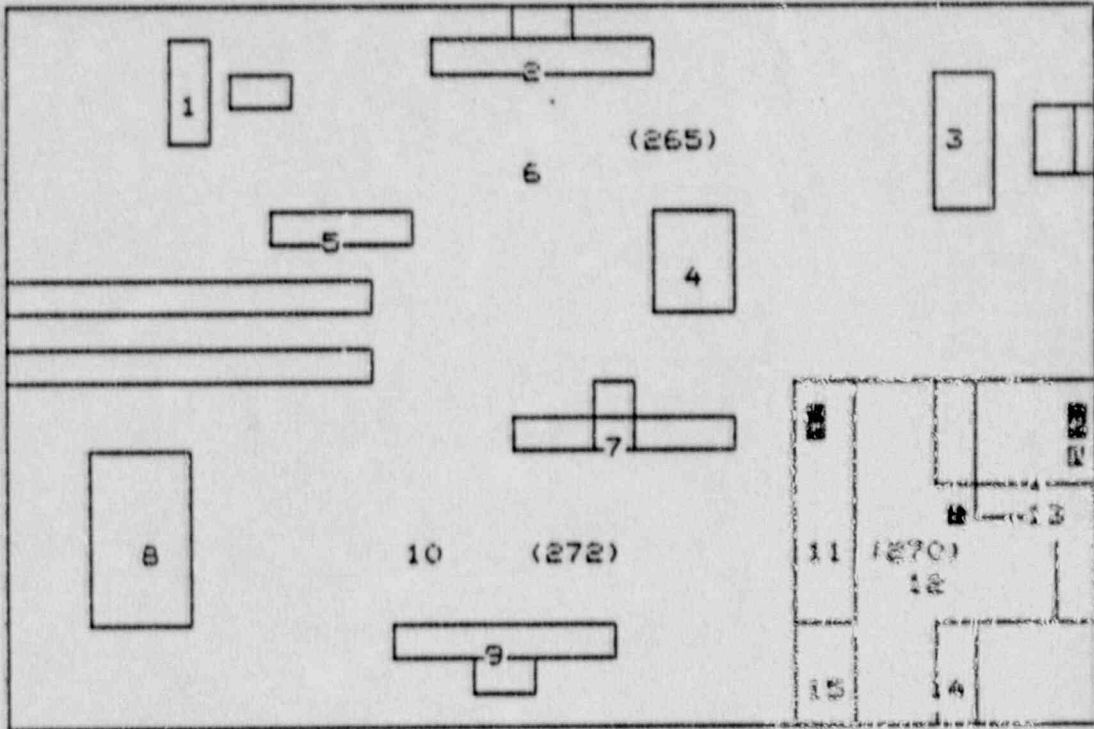
LOCATION	DPM/100cm ²
1. SINK	-----
2. BENCH	-----
3. HOOD	-----
4. GENERATOR	-----
5. WASTE	-----
6. SHIELD	-----
7. BENCH	-----
8. BENCH	-----
9. FLOOR	-----
10. FLOOR	-----
11. FRIDGE	-----

TRIGGER LEVEL 2000 DPM/100cm ²

REMARKS:
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DATE: -----
 TIME: -----
 INITIALS: -----
 METER: -----

NUCLEAR CARDIAC AREA (WHITE 265&272)
 CELL LABELING LAB (WHITE 270)



LOCATION	DPM/100cm ²
1: TABLE	-----
2: TABLE	-----
3: TABLE	-----
4: TREADMILL	-----
5: TREADMILL	-----
6: FLOOR	-----
7: TABLE	-----
8: TABLE	-----
9: TABLE	-----
10: FLOOR	-----
11: BENCH	-----
12: FLOOR	-----
13: BENCH	-----
14: BENCH	-----
15: HOOD	-----

TRIGGER LEVELS
 2000 DPM/100cm²

REMARKS:

DATE: -----
 TIME: -----
 INITIALS: -----
 METER: -----