

MASSACHUSETTS GENERAL HOSPITAL

I ROBERT BUCHANAN, M.D. General Director

Boston, 02114 Telephone (617) 726-8326

Cable Address "Massgenral"

October 31, 1990

U. S. Nuclear Regulatory Commission Region I Division of Radiation Safety and Safeguards 475 Allendale Road King of Prussia, PA 19406

Subject: Inspection #90-001

Attn: Mohamed M. Shanbaky

Gentlemen.

We are responding herewith to your letter dated October 3, 1990 and the attached Appendix A, Notice of Violation, which lists three (3) violations.

Our response consists of two parts: A. comments on the third paragraph on page 1 of your letter regarding uncorrected violations; and B. responses to each of the alleged violations including corrective steps as specified in the last paragraph on page 4 of your letter.

These two parts are appended to this letter of response.

Yours sincerely,

M. Spicer

Assistant General Director for

Safety and Regulation

EWW/bh Enc.

9102270140 910211 REQ1 LIC30 20-03814-80 PD PDR

A. General

We recognize that in our Broad License Application dated June 29, 1983 we agreed that Nuclear Medicine area surveys would be conducted weekly employing wipe tests, and that there was a period in 1989 when such weekly surveys were not performed as noted in the July 1989 inspection. Corrective action was taken and these surveys have been regularly performed since the 1989 inspection. However the area currently cited in Violation 1 is not in Nuclear Medicine (2nd Floor, White Bldg.) but is in Room B15A in the basement of the Edwards Bldg. which is utilized by the Thyroid Unit (Dept. of Medicine) for preparing Iodine-131 for treatment of thyroid disease. Therefore in our view the finding in Violation 1 is not strictly a "recurrence" of the previous violation and does not indicate that our previous corrective action was ineffective. Nevertheless we do agree that there was a lapse in the weekly wipe-testing of the area used by the Thyroid Unit (see below).

Responses to each of the alleged Violations 1, 2, and 3 follow.

B. Specific

This violation is admitted and the circumstances explained below. For many years the subject Room B15A was surveyed weekly by the staff of the Harvard University Environmental Health Service (HUEHS) including wipe tests of potential radionuclide use reas. In addition, the staff of the Thyroid Lab. have habitually performed instrumented area surveys in this room following each preparation of a therapeutic dose of Iodine-131, but without conducting wipe tests. However, recently the B15A laboratory war .dified by separating from it a small enclosed area (B15B) or conducting iodinations. This small adjoining area is regularly wipe-tested weekly by HUEHS personnel. Unfortunately, due to a misunderstanding, the HUERS staff at the time of the change reduced its survey vipe-testing frequency in B15A from weekly to monthly. Nevertheless the instrumented survey by Thyroid Unit personnel after each I-131 dose preparation has continued and the results are still recorded. To show this we enclose a copy of a sample page from the Thyroid Unit record book for the period April 13, 1990 to May 24, 1990 (Attachment #1).

Action taken. Instructions were given to the HUEHS staff immediately after the August 1990 inspection to resume the weekly wipe tests in B15A. These are now proceeding satisfactorily as evidenced by the attached typical HUEHS survey report for dates 9/14, 9/21, 9/28/90) (Attachment #2). In addition the technologists in the Thyroid Unit are also recording data from wipe tests taken in B15A after each I-131 therapy proparation (Attachment #3).

2. We admit this violation particularly for the period January 17 1990 to May 2, 1990. During that period there were occasional biossay attendance lapses by the 2 technologists in the Thyroid Unit who have handled or administered the therapeutic doses. There was however a lengthy period during which the physicians responsible for these therapeutic administrations did not present themselves for thyroid assay, partly because they did not handle the radioactivity and partly because the previous Radiation Safety Officer had excused them since they were not in close proximity to the patient during the administration. After May 2, 1990 there was a marked improvement in timely attendance for thyroid assay particularly by the responsible physicians. A summary record of assays is attached (Attachment #4):

Action taken. On August 31 the Chairman of the Radiation Safety Committee informed the physicians in the Thyroid Unit that attendance for thyroid scans within 3 days of administration of a cancer therapy dose of I-131 was mandatory (see Attachment #5). A similar written reminder, following an oral instruction, was sent to the technologists involved (Attachment #6). An updated I-131 therapy sheet is also enclosed (Attachment #7). This new form will make it easier for the Radiation Safety Office to assure compliance of thyroid monitoring.

We are not persuaded that the relatively high thyroid burdens experienced by two technologists in the Nuclear Medicine Research Area conducting I-125 iodinations in a particular hood in early August was due to the employment of inadequate engineering controls." We maintain that the increasing I-131 burders culminating in 90 and 30 nCi on August 9 were the subject of concern and joint action by the REO and Nuclear Medicine Division in late July 1990. We are doubtful that the cause of these elevated burdens was the installation of lead strips over the lower hood vents on July 23, 1990. Mr. W took this action to reduce the (small) exposure rate in the room behind the hood without consulting or notifying the RSO. The inspector- believed that this action should have been discovered earlier by the Radiation Safety Office and the lead removed. They also believed that Mr. W's head position when doing iodinations was improper and contributed to his I-125 intake.

At the close of the inspection it was pointed out that the positive radioiodine uptakes by Mr. W and Ms. N were noted by the Asst. PSO during the weeks of July 23 and July 30 (13.8 nCi and 30.6 nCi). The elevated readings were attributed by the RSO to an inadequacy of the hood ventilation. Therefore on Friday August 3rd in a conference held in the MGHE Nuclear Medicine area, the Asst. RSO proposed that a glove box (minihood) with integral charcoal trap and pump should be

incorporated into the hood at which Mr. W was working. Also proposed to Dr. S at that time was the purchase of charcoal cartridges for the venting of the vials containing RaI. These plans were further developed during the week following (i.e. Monday, August 6 - Friday, August 10) when a catalog from the Atlantic Nuclear Corporation arrived and a tentative choice of the IH-120 hood was made. However, on August 9 an increased thyroid burden of 90 nCi for Mr. W was noted by Mr. Johnson (Harvard University Health Services), with a smaller burden of 30 nCi for Ms. N. On Friday, August 10 therefore several actions were taken: (1) Mr. W's thyroid was recounted, (2) Mr. W was suspended from using I-125 for one month, when the new count showed 99 nCi, (3) Air Systems Services was requested to measure the air flow if possible on Monday, August 13; (4) orders were given to remove the frontal lead in the hood to facilitate the air flow measurement and to prevent possible irregulatories in the air flow.

The visit of the inspectors to MGH East - 5th Floor occurred on the following Monday August 13 at which time most of the lead at the front of the hood had been removed and other corrective actions were in process. It was Mr. W who suggested to the NRC inspector that the placement of lead bricks at the end of July at the front of the hood and possibly the lead sheet at the rear of the hood may have caused the increase in uptakes. Is is clear however that there had been intensive follow-up of the relatively recent I-125 internal contamination for more than one week (August 3 - August 10) before the inspection date. It must be admitted that most users of the hood and all of the nuclear medicine and radiation safety staff involved, believed that this hood was of the usual design with a top vent only. Therefore during the conferences on August 3 and 10 the lead at the rear of the hood was not mentioned. On the other hand it is not clearly established that the personal contamination of the two users in the period 7/26 through 8/9 was due to the installation of the lead sheet since 3 other users in this period did not show high _hyroid activity. It was more likely due to poor iodination technique.

The proposed installation of the minihood is now finalized; a purchase order was submitted on Tuesday, August 14 (Attachment #8) and sent out by the Purchasing Dept. on August 26 (Attachment #9). This minihood has now been received and will soon be installed. Attachment #10 gives a recent follow-up on the main hood including the most recent readings of Mr. W and Ms. N. Both thyroid burdens are now considerably lower.

In summary: (a) we were well aware of the elevated thyroid burdens of two out of five hood users,

(b) we had decided to install a minihood inside this hood

more than one week before the inspection.

- (c) we are not convinced that the installation of a lead sheet which covered the rear hood vents was the cause of the elevated burdens but was more likely due to poor iodination techniques.
- (d) the corrective actions we have taken include installation of the minihood and use of chargoal filters to vent I-125 vials. Some of the hood lead was removed before the inspection.
- (e) we expect to determine whether these corrective measures are effective through follow-up of thyroid assay results during the month of November 1990.

EWW/bh

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HARVARD UNIVERSITY RADIATION PROTECTION OFFICE 46 DXFORD ST. CAMBRIDGE, MA 02138 - (617)-495-2060 LABORATORY SURVEY REPORT

TO: DR. GILBERT DANIELS , MGH 12000.00 CPM 10 HD0D SERIES CODE: MDA

LAB: RESEARCH BO15A

SURVEY DATE: 90/09/14 BY JV

FINDINGS: NO ADDITIONAL COMMENTS.

VIOLATIONS: NO VIOLATIONS OBSERVED.

ACTION TAKEN: NO ITEMS REQUIRING ACTION WERE OBSERVED.

RP# VALUE UNITS DIST(CM) FROM OBJECT WIPE RESULTS(DPM) CHAN NO.

LAB: RESEARCH BOLSA

SURVEY DATE: 90/09/21 3Y JV

FINDINGS: NO ADDITIONAL COMMENTS.

VIOLATIONS: NO VIOLATIONS OBSERVED.

ACTION TAKEN: NO ITEMS REQUIRING ACTION WERE OBSERVED.

RPH VALUE UNITS DIST(CM) FROM OBJECT

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WIPE RESULTS (DPM) CHAN NO. 15625.0

LAB: RESEARCH (BO15A)

BURVEY DATE: 90/09/28 BY JV

FINDINGS: NO ADDITIONAL COMMENTS.

VIOLATIONS: NO VIOLATIONS OBSERVED.

ACTION TAKEN: NO ITEMS REQUIRING ACTION WERE OBSERVED.

RP# VALUE UNITS DIST(CM) FROM OBJECT WIPE RESULTS(DPM) CHAN NO.

1. Wipe tests are made over large working areas

2. Only tests recording > 100 dpm are reported

3. For wipe tests exceeding 1000 dpm the area is decontaminated on follow-up.

Robert I Johnson

HARVARD UNIVERSITY RADIATION SAFETY OFFICE

Criteria for Reporting Swipe Results.

- 1) 100dpm or greater: include results in the survey report.
- 2) 1000dpm or greater: report the result to the appropriate Radiation safety office and to the investigator in DPM. Include the swipe results in your survey report. Note in the survey report that the Radiation Safety Office and investigator have been notified.
- DPM, to the appropriate Radiation safety office, and the investigator. Enter the initial survey separately from the follow up survey. Perform a follow up survey. When entering this survey note it as a follow up to swipe results with high positive readings. Also note in the survey report that the RSO and investigator have been notified.

DPM calculation: CPM = DPM Eff

- 11.27 Survey areas of the laboratory that are designated for radioactive use, including but not limited to: benches, centrifuges, incubators, hoods, liquid scintillation counters, refrigerators, and sinks. If you find any readings from a sink drain, without a corresponding sink disposal entry, refer to Appendix 1 to determine if you have found a violation. If you find smaller items such as glassware or pipettors that give above background readings, and are unlabelled, attach a "radioactive" tape label. This will help to keep contaminated equipment out of areas where radioactivity is not used. If you determine that radioactive items have been left unlabelled and unattended for at least 8 hours, refer to Appendix 2 and cite the violation: Radioactive Materials Not Labelled.
- 11.28 Survey areas of the laboratory that are not used for radioactive work, including but not limited to floors, desks, door handles, sink handles and phones, trash cans. Use a NaI probe to monitor sink drains and trash cans. If you find any readings above background from materials in the conventional trash, refer to Appendix I. Ensure that Time, Distance and Shielding are being used to limit your exposure. Remind workers to limit their time near the source, and to increase their distance from the source. Ensure proper shielding is being used in all directions that can result in exposure of laboratory personnel.
- 11.29 If you find a reading above Background that may be the result of contamination rather than specific sources, check for removable contamination by wiping the area with a piece of paper towel and reading the swipe with your meter. If you get a reading ask laboratory personnel to clean up the removable contamination. Dispose of the paper towel in the radioactive trash. Any nonremovable contamination must be shielded and labelled as radioactive. Record on your survey sheet any actions you've taken or any actions taken by laboratory personnel, such as decontaminating or shielding.
- 11.30 Check for removable radioactive contamination using wipe tests.
 - 11.30.1 Label a coin envelope with the laboratory room number.
 - 11.30.2 Remove the swipes from the envelope.
 - 11.30.3 The number of swipes taken in a laboratory

depends on the size of the laboratory, the frequency of the survey, and levels of contamination typically detected. Swipes will include items representing both "radioactive-use" and "nonradioactive-use" areas. Four swipes is an average but some rooms may require fewer or greater than four. For example, rooms with only one or two pieces of equipment may require only 2 swipes, while rooms with 8 bench areas may require 8 swipes. Use your best judgement to insure the lab has been evaluated adequately.

- 11.30.4 Using a Whatman #1 4.25 cm filter paper (swipe) hold the edge between your thumb and index finger, draw the filter paper with the numbered side up across the surface to be tested in a smooth sweeping action pressing lightly against the surface. The area swipec is not limited to a certain value, but it should be greater than 100 cm.
- 11.30.5 Fold each swipe in half, with the potentially contaminated side folded to the inside, and put it back in the coin envelope.
- 11.30.6 Hold the envelope in front of your probe to check for a dose rate coming through. If you do not pick up a reading, continue. If you do pick up a reading, place the envelope in your briefcase to be returned to EH&S. Go back to survey the areas you swiped, checking for removable contamination. Refer back to the Sections 8.10.2 and 8.10.3 in these Procedures. Do not swipe an areas of known contamination.
- 11.30.7 Record each swipe on your survey sheet, indicating the actual item swiped, and its corresponding reference point number taken from that lab's Reference Point Map. It should be noted that a swipe is not limited to one RP point.
- 11.31 Change Sink Disposal Records (Form 200.2) that are half full or are more than 3 months old. Change all sink disposal records in December.
 - 11.31.1 Make sure that the permit holders name, bldg, series code, and room number are properly recorded on form 200.2.

by Packard Service Representative on 9/6/90. Jgs.

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40						0/2		
2/15						8/9		

Summary record of thyroid cancer treatments and attendance for thyroid scans

Cancer Rx date		Physician Received Scan	Technologist Received Scans				
	1/10/90	No	1/12 (A)				
	1/16/90	No	1/18 (A)	1/18 (M)			
	1/23/90	No	1/24 (A)	1/24 (M)			
	2/5/90	No	2/28 (A)	2/28 (M)			
	3/6/90	No	4/4 (A)	4/4 (M)			
	4/9/90	No	None				
	4/11/90	No	4/25 (A)	4/25 (M)			
	5/2/90	No	None				
	5/16/90	Yes (5/31)	5/18 (A) 6/1 (A)	5/18 (M) 6/1 (M)	******		
	6/6/90	Yes	None				
	6/13/90	Yes	(A) (no date)	6/15/ (M)			
	7/10/90	No	None				
	7/18/90	Yes	7/20 (A)	7/20 (M)			
	7/25/90 7/25/90	Yes No	(A) (no date) (A) (no date)				
	8/6/90	Yes	(A) (no date)				

⁽A) and (M) are Thyroid Unit technologists

Eachment 5



MASSACHUSETTS GENERAL HOSPITAL

J. ROSERT BUCHANAN, M.D. General Director

Boston, 02114 Telephone (617) 726-8326

Cable Address "Mass, anral"

August 31, 1990

To:

Thyroid Unit Staff

From:

Chairman, Radiation Safety Committee

Subject:

Thyroid scans are mandatory after administration of large therapy doses

(> 30 mCi for Rx thyroid cancer

During the inspection by the Nuclear Regulatory Commission from August 13 to August 15, 1990, it was observed that there were no records of thyroid gland assays (for I-131) having been performed in the period January 1, 1990 through May 5, 1990 on the physicians involved in thyroid cancer therapy with doses in the range 75--150~mCi of I-131 (and also during the preceding 6 month period). The records over this extended period also indicated that there were a few missing records for the Thyroid Unit technologists who are involved in preparation and administration of these doses. As a consequence it is almost certain that the Hospital will be cited for a violation of NRC regulations, although the claim has not yet been received. Two regulatory points must be brought to your attention.

I. Title 10, Part 35 of NRC Regulations: Item 35.315(a)(8) as follows:

"Measure the thyroid burden of each individual who helped prepare or administer a dosage of Iodine+131 within three days after administering the dose, and retain for the period required by 20.40(c)(1) a record of each thyroid burden measured, and the initials of the individual who made the measurements."

II. Condition #1 of the Human Use Permit #89-087 issued to the Thyroid Unit which states "Any person preparing materials containing 30 mCi or more of I+131 must have a thyroid assay within 3 days by arrangement with the Radiation Safety Office, ext. 6-2425.

The record shows that attendance for thyroid assays in the period since May 16, 1990 has been reasonably good (but not perfect). I attach a summary record which I have prepared for the period 1/1/90 through 8/6/90, which shows the deficiencies.

I cannot emphasize enough that the above rules must be followed. If further delir pencies are observed the Radiation Safety Office will issue internal MGH violations, which could result in a permit suspension after 3 such violations.

EWW/bh Attachments

MASSACHUSETTS GENERAL HOSPITAL

5 USN

J. ROBERT BUCHANAN, M.D. General Director

Boston, 02114 Telephone (617) 726-8326

Cable Address "Massgenral"

September 18, 1990

To:

Thyroid Laboratory Technicians

From:

Acting Radiation Safety Officer

Subject:

Attendance for I=1 7 Thyroid Scans

Michele Celello has mentioned to me that she has emphasized to you soon after the recent NRC inspection that thyroid scans are required by the NRC within 3 days of preparing/administering a dose of I-131 for cancer therapy. I would like to add my own urging to you and anybody else in your laboratory who handles I-131 routinely to attend for thyroid scans on a once per week basis (for example every Thursday). Thursday is a good day because it is 3 days away from an I-131 therapy which could be done on a Monday. Please call Michele Celello to arrange this (6-2425).

EWW/bh Attachment

cc: M. Celello

R. Johnson

Radiopharmaceutical Therapy I-131

Nurse Manager notified room is cleared

Room closed for further Decontamination



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FORM 10796 Rev. 8/78

MASSACHUSETTS GENERAL HOSPITAL

ORDER NO.

DATE: 14 15 10

REQUEST FOR SPECIAL FUND PURCHASE

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WHITE - Purchasing Department

CANARY - Fund Section

PINK - Retain by Requestor

ATTACHMENT #8

P0104/54

MASSACHUSETTS GENERAL HOSPITAL

OPERATED BY THE GENERAL HOSPITAL CORPORATION IN BOSTON

6705834

SHIP TO:

MASSACHUSETTS GENERAL HOSPITAL

121 INNERBELT RD RECEIVING AREA 1

SOMERVILLE MA 02143

ATTN:

MGH EAST NUCLEAR MED FLR 5420

TO:

ATLANTIC NUCLEAR CORP 6 VILLAGE GATE ROAD

CANTON

MA 02021

46525

05 *5 Attachment #9

Page

ATTENTION REQUESTOR:

This copy is your record. Please refer to Purchase Order number when checking with Purchasing. See below for receiving instructions.

NOTE: All prices are confidential and for M.C.H. personnel use only, please.

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RECEIVING INSTRUCTIONS

PLEASE CHECK RECEIVINGS AGAINST PACKING SLIPS FOR ACCURACY:

REPORT - SHORTAGES BY TELEPHONE TO MATERIALS MANAGEMENT RECEIVING X2274.

REPORT - DAMAGED GOODS WITHIN 48 HOURS TO THE BUYER AT FURCHASING - SAVE ALL PACKAGING MATERIALS!

PURCHASE ORDER NO.

6705834

BUYER

D LAFONTAINE TELEPHONE617-726-2268

MATERIALS DELIVERED DIRECTLY TO DEPAP, MENT OR PICKED UP FROM VENDOR MUST BE DOCUMENTED ON A COPY OF THIS ORDER MAIL SIGNED COPY TO MATERIALS MANAGEMENT RECEIVING CONTROL-GRAY BASEMENT.

Egg the record October 30, 1990

UPDATE ON IODINATION ACOD INVESTIGATION

Nuclear Medicine, MGH-East

B.W.: 12.6nCi 10-30-90 (1-125) W.N.: 2.6nCi 10-30-90 (1-122)

The lead sheets covering on the vents were removed on 8-1/-90.

The hood air flow has been re-measured by the Maintenance Department of MGH-East. The flow rate was 100 LFM. In addition the Mini-hood arrived on October 29.

B. W. was given a written iodination procedure and instructed not to lean into the hood while working and to lower the sash below the breathing zone (12").

N.N. was observed by Dr. K. and instructed to decrease movement in the hood and place the source (I-123) further back into the hood.

Charcoal traps were purchased to vent viale. Sharps are no longer stored in hood.

Michele J. Celello

Michely Callle

Assistant Radiation Safety Officer

IDDINATION HOOD INVESTIGATION

August 10, 1990

Strauss/Khaw, MGH-East, 5th floor

8-9-90 Bob Wilkinson 90.2 nCi 8-9-90 Nessie Nossif 30.6 nCi 8-10-90 Bob Wilkinson was suspended from using iodine for one month.

Flow rate: Checked by Air Systems Services scheduled for 8-9-90.

Suggested: Mini-hood (Atlantic Nuclear)
Charcoal traps for vial (NEN)
Charcoal traps for liquid waste

Bricks in hood may be causing turbulance; these will be removed and a mini-hood with a front panel of leaded acrylic will be installed.

Liquid vaste vill also be removed on Monday, August 13, 1990.

Wipe tests were performed on the hood on August 10, 1990. The hood was then decomtaminated. Meter surveys are done in this lab on a daily basis. Wipe tests are done weekly.

Machelo J. Celello

P.S. 8-20-90
The new minihood for installation in the MGH-6-5 hood was finally ordered today.

MJC

MASSACHUSETTS GENERAL HOSPITAL Radiation Safety Office

REQUIRED IDDINATION PROCEDURE

- All iodinations must be done in an approved iodination hood. Hoods must be under negative pressure with a face velocity of 90 - 110 LFM.
- 2.) Fill in the log book in your lab.
- Never leave the hood from start to finish during an iodination.
 Have all equipment in the hood before hand. Monitor the hood before you begin to ensure there is no contamination.
- 4.) Keep large objects out of the hood since they may creete turbulance. Lead bricks are not recommended.
- 5.) Use absorbent pads to minimize contamination.
- 6.) Wear a lab coat, double gloves and any required dosimeters.
- 7.) Maximize your distance from the source and minimize time spent. (A ImCi I-125 source unshielded will read 0.7 mR/hr at 1 ft.; a chest x-ray is 20 mR).
- 8.) Minimize the evolution of radioiodine consistent with proper pH and temperatures. Cap all open containers after the reaction. Enter the vial through the septum whenever possible. Charcoal traps may be used to vali the vial if uncapping is necessary.
- 9.) Double bag all dry waste and dispose in radioactive drums. Liquid waste may be poured down the sink in accordance with sink limits.
- 10.) In the event of a power failure or arge spill during an indination: hold breath, contain the spill with charcoal/absorbent mixture, close the hood, evacuate yourself and personnel from the room. Close the lab door and notify the Radiation Safety Office immediately (x6-2425).
- 11.) After the iodination, monitor hands, lab coat, hood and equipment thoroughly. Any radioiodine that adheres to the hood, may still be released. A NaI probe is recommended for monitoring.
- 12.) Have your thyroid scanned by appointment with the Radiation Safety Off.je (West End House-Basement). If you perform indinations with I-125 you must have your thyroid scanned within one month; for I-131 within 72 hours, and for I-123 within 24 hours. Nonthly thyroid scans are scheduled the last Wednesday of each month in Boston and the last Friday of each month in Charlestown (5th floor).