30 Prospect Avenue
Hackensack, N.J. 07601
201.996.2000

Affiliated with the
University of Medicine and
Dentistry of New Jersey -
New Jersey Medical School

Member of the
New Jersey Council of
Teaching Hospitals

REPLY TO A NOTICE OF VIOLATION

May 2, 2005

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, D.C. 20555

Reference Docket Number : 03002452
Reference License Number : 29-02641-03

To whom it may concern,

This letter is in response to the notice of violation sent to our facility on April 19, 2005.

Response to infraction against 10 CFR 20.1301(a) (2).

a. The individual performing the radiation protection survey did not use the correct occupancy factors when calculating the dose to unrestricted areas. In addition, the individual did not indicate the justification for using such occupancy factors. In addition to 10 CFR 20.1201(a) (2), Hackensack University Medical Center internal policy regarding the use of radioiodine clearly states that the dose in unrestricted areas shall be below 2 millirem in any one hour. See Enclosure A item number 28.

b. Radiation Safety personnel at Hackensack University Medical Center have been in-serviced about the contents of the policy regarding radioiodine administrations. The following issues were addressed during this in-service :

1. The nursing staff on three main south are considered to be occupationally exposed workers.

2. Radiation Safety personnel shall instruct Nursing that visitors are not allowed during the treatment.

3. Immediately after administration Radiation Safety personnel shall perform a radiation survey of the area surrounding the patient's room. No unrestricted area shall have radiation levels in excess of two millirems in any one hour. Rolling lead shields shall surround the patient to reduce exposure rates to

unrestricted areas to less than two millirems in any one hour. Exposure rates shall be measured at the patient's bedside, the surface of the patient, one meter from the patient, adjacent rooms and the entrance to the room. Radiation Safety personnel shall put a Radioactive Material sign on the door of the patient's room. A record of the survey shall be kept on file for three years.

See Enclosure B Signature Sheet for In-Service.

A radioiodine administration occurred on 3/21/05 after corrective action was taken. The results show that the exposure to unrestricted areas was maintained below two millirems in any one hour. See Enclosure C for Survey Results.

4. Hackensack University Medical Center is currently in compliance with 10 CFR 20.1301(a) (2).

If you have any questions regarding this mater you can reach me at (201) 996-2548.

Sincerely yours,

Eric Weiss

Eric Weiss, M.S., D.A.B.R.
Director of Diagnostic Physics
Radiation Safety Officer

HACKENSACK UNIVERSITY MEDICAL CENTER
DEPARTMENTAL MANUAL

NUCLEAR MEDICINE DEPARTMENT Iodine 131 Administrations

POLICY:

This policy outlines the administrative responsibilities and radiation safety practices associated with the administration of iodine 131.

PROCEDURE:

Whole Body Scan

1. The dosage for the scan is to be determined by the ordering endocrinologist (on staff H.U.M.C.).

2. Patient preparation is determined by the ordering endocrinologist (on staff H.U.M.C.).

3. Female patients between the ages of 12 and 65 must have a pregnancy test performed one day prior to administration.

4. Prior to scheduling the administration, a written directive and recent uptake must be available in the Nuclear Medicine Department.

5. Imaging will occur at 48 hours post administration.

Thyroid Therapy >30mCi

1. Prior to scheduling, the ordering endocrinologist shall consult with the Radiation Safety Officer to determine if the patient is a candidate for outpatient therapy. The Radiation Safety Officer will require a written directive.

2. It is the sole responsibility of the Radiation Safety Officer to determine if the patient will be treated on an inpatient or outpatient basis.

3. The Radiation Safety Officer shall interview the patient and evaluate the patients living conditions. The results of this interview will determine the occupancy factor that will be used in calculating the release criteria. Documentation of this interview shall be kept on file for three years post therapy (See enclosure A).

4. Using the occupancy factor obtained in the previous step the Radiation Safety Officer must complete a case specific calculation prior to administration. The result of this calculation must be below 500mrem as required by Nuclear Regulatory Guide 8.39, "Release of Patients Administered Radioactive Containing Materials". Documentation of this calculation shall be maintained on file in the Radiation Safety Office for three

years post administration (See Enclosure B). If calculation exceeds 500mrem the therapy must be performed as an in-patient.

5. A pregnancy test must be performed on the day of administration. The results of the pregnancy test shall be documented on the written directive (See Enclosure C).

6. The treatment dose is to be determined by the endocrinologist.

Thyroid Therapy >30 Outpatient Status

7. Administrations can occur Monday - Friday.

8. Written as well as verbal instructions regarding radiation safety shall be given to the patient prior to administration (See Enclosure D). A copy of the written instructions shall be signed by the patient in the presence of the Authorized User to verify comprehension of the instructions. A copy shall be maintained on file in the Radiation Safety Office for three years post administration.

9. The patient shall leave hospital immediately after receiving the dose.

10. The patient must drive directly home alone, without making any stops.

Thyroid Therapy >30 Inpatient Status

7. Administration can only occur on Monday, Tuesday, or Wednesday.

8. The referring endocrinologist must make all necessary admitting arrangements, specifically regarding patient location. The only available location for the treatment of a patient receiving radiopharmaceutical therapy is three main south.

9. Admission Services has the responsibility to assign the patient a private room with a toilet at the end of a corridor. The patient shall be confined to the room during the course of treatment.

10. Radiation Safety personnel shall use leak proof absorbent paper to cover large surfaces that are likely to be contaminated such as chairs, and the floor around the toilet. Small items such as telephones, door knobs, bed remote control, television control, and the nurses call cord should be covered with plastic.

11. The nursing staff on three main south is considered to be occupationally exposed workers.

12. Nursing shall have the responsibility to provide disposable gloves, booties, isolation gowns, and red bags in close proximity to the room for use by Nursing, Radiation Safety Personnel, and Physicians.

13. Radiation Safety personnel shall provide nurses caring for the patient with film badges. At no time are badges to be exchanged between nursing personnel. Each individual should write their name onto the record sheet provided. The head nurse should check that this form is completed. The film badges and record sheet shall be collected at the end of the treatment.

14. Radiation Safety personnel shall instruct Nursing that visitors are not allowed on any part of three main south during the treatment.

15. Nursing shall notify food services that disposable utensils and service trays shall be used for this patient.

16. Nursing shall assure that a plastic red bag shall be kept at the entrance of the room for all disposable items such as plates, eating utensils, cups, napkins, tissues, bandages or dressings, etc. This material shall be periodically collected and monitored by Radiation Safety personnel and be stored in a low level radioactive waste facility located on the hospital premises.

17. The patient shall be instructed by Radiation Safety personnel that he/she may use the toilet as usual but must flush three times.

18. Dietary, food handlers, and housekeeping are forbidden to enter the room during the course of treatment.

19. Nursing, Radiation Safety Personnel, and Physicians are the only staff allowed in the room during the course of treatment.

20. Protective gloves and booties must be worn when entering the room during the course of treatment.

21. In addition, Radiation Safety personnel must wear a protective gown during clean up post treatment.

22. These protective garments must be disposed of in the receptacle located at the entrance of the room prior to exiting.

23. Thermometer, stethoscope and blood pressure cuffs must be kept inside the room during treatment and can not be interchanged with any other patient.

24. Nurses who are pregnant are not allowed to care for the patient.

25. The referring endocrinologist must be aware that no diagnostic examinations can take place during the course of treatment e.g. chest x-ray and blood work.

26. Emergency numbers shall be posted at the entrance to the room.

27. Nursing shall be in-serviced about Radiation Safety. A signature sheet maintained on file for three years.

28. Immediately after administration Radiation Safety personnel shall perform a radiation survey of the area surrounding the patient's room. No unrestricted area shall have radiation levels in excess of two millirems in any one hour. Rolling lead shields shall surround the patient to reduce exposure rates to unrestricted areas to less than two millirems in any one hour. Exposure rates shall be measured at the patient's bedside, the surface of the patient, one meter from the patient, adjacent rooms and the entrance to the room. Radiation Safety personnel shall put a Radioactive Material sign on the door of the patient's room. A record of the survey shall be kept on file for three Years (See Enclosure E).

29. If patient dies while containing the radioactive material, the Radiation Safety Officer shall be consulted on instructions for the funeral director or pathologist.

30. If the patient vomits within 24 hours after receiving the radionuclide treatment the following steps must be taken:

    a. Place absorbent pads over the vomit.
    b. Leave the room.
    c. Notify the Radiation Safety Officer immediately.
    d. Vomit and other contaminated material shall be handled as radioactive material and proper precautions shall be taken.

31. Radiation Safety personnel shall instruct the patient not to handle small children or infants for one week after the therapy. Do not release any patient until their exposure rate is less than 5mR per hour at 1 meter or the retained activity is less than 30mCi.

32. When the patient is discharged the Radiation Safety Officer or other qualified staff member shall:

    a. Survey room before releasing it for clean-up and a new admission.
    b. Decontaminate if necessary.
    c. Collect the nurse's film badges.
    d. Remove the signs from the door.

<u>Thyroid Therapy < 30mCi</u>

1. Patient preparation is determined by the ordering endocrinologist.

2. Female patients between the ages of 12 and 65 must have a pregnancy test performed one day prior to administration.

3. Prior to scheduling the administration, a written directive and recent uptake must be available in the Nuclear Medicine Department.

4. Administration days can only occur Monday - Friday.

5. Written as well as verbal instructions regarding radiation safety shall be given to the patient prior to administration see enclosed instruction sheet for details. A copy of the written instructions shall be signed by the patient in the presence of Nuclear Medicine Technologist to verify comprehension of the instructions. A copy shall be maintain on file in the Nuclear Medicine Department for three years post administration.

Hackensack University Medical Center
30 Prospect Avenue, Hackensack
New Jersey 07601

Date : March 18, 2005

An in-service education lecture was presented on the following subject matter:

Iodine 131 Administrations

The duration of the in-service was : 30minutes

Attendance included the following personnel :

Jessie Trivino, M.S., D.A.B.R.
Associate Physicist

Tod Richards, M.S.
Associate Physicist

Denise Litts, C.N.M.T.
Physics Assistant

Charles Mateo, R.T.
Physics assistant

The in-service was presented by :

Eric Weiss, M.S., D.A.B.R
Director of Diagnostic Physics
Radiation Safety Officer

NURSING INSTRUCTIONS, SURVEY & DOSIMETRY FOR PATIENTS TREATED WITH NAI-131

Floor: 3 SOUTH **Patient Room No.:** 3306

Dose Administered (mCi): 149 **Date:** 3/21/05

Authorized User: D'ASIAN **Time:** 3:00

Date	Time	Exposure Rate (mR/hr)						Comment
		Restricted Areas				Unrestricted Areas		
		At Contact	3 ft Away	Bedside	Door	Left Adj. Rm.	Right Adj. Rm.	
3/21/05	3:00 PM	220	20 30cm	28	0.34	0.13	0.27	
3/22/05	1:00 PM	60	5.5	8 cm	0.1			
3/23/05	8:50 AM	26	1.9					

Survey Meter Used: Manufact.: VICTOREEN Model: 450B

S.N.: 2117 Date of Last Calib.: 8/16/04

INSTRUCTIONS

Nursing Instructions:

- ✓ Patient restricted to room
- ✓ No pregnant nurse may render care
- ✓ 300 minutes each day per nurse in the room
- ✓ Wear disposable gloves, booties, ~~and gown~~
- ✓ Wash your hands after caring for patient.
- ✓ Wear the radiation monitor when caring for the patient.
- ____ ____

Visitor Restrictions:

- ✓ No Visitors Allowed

Patient Care:

- ✓ Discard linen, bedclothes, plates, utensils, dressings, etc. in containers inside the room
- ✓ Other hospital personnel such as housekeeping, lab technician, etc are not allowed to enter the room
- ✓ Only RSO or his designate may release the room to housekeeping

In case of emergency, or if you have a question, call:

Jessi Trvino 991-5720

Radiation Safety Officer: Eric Weiss, M.S. Work #: 996-2548 Pager #: 973-591-8384

Authorized User: D'ASIAN Work #: ____ Pager #: ____

	Date	Time
Patient Released:	3/23/05	11:00
Room Released for Cleaning:	3/23/05	12:30

Exposure Rate at 3 ft away at time of release (E_R) = 1.9 mR/hr Effective Half Life (T_{eff}) = 13 hr

Occupancy Factor (F) = 0.25

Dose to Public from the Released Patient = 1.44 x E_R x T_{eff} x F = 1.44 x 1.9 x 13 x 0.25 = 8.89 mR

Is dose to the public less than 100 mR?: (Yes) No

Signed: ____

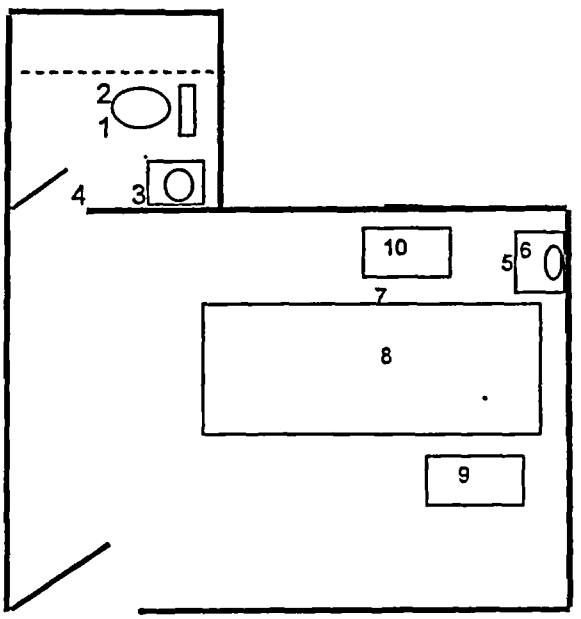
Medical Physicist

CLOSEOUT SURVEY and WIPE TEST
After I-131 Therapy

Date: 3/23/05 Patient: _____ Dose (mCi): 150
Floor: 3 South Link Room #: 3306

Ssurvey Meter Used: Ludlum 3 GMPC Well Counter Used: Capintec Well Counter
S..N.: ~~[illegible]~~ 213885
Date of Last Calibration: 19JAN05

Diagram:



Results:

Area	Location	Radiation Survey (mR/hr)	Wipe Test (dpm)
	Background	0.03	-
1	Toilet Seat	0.10	74
2	Toilet Floor	0.03	0
3	Sink 0.07 (BASIN)	0.15 (STRAINER)	25
4	Door Knobs	0.05	0
5	Nightstand	0.03	0
6	Telephone	0.03	9
7	Bed Floor	0.04	18
8	Bed	0.04	31
9	Table	0.03	9
10	Sofa	0.04	34
	Limit >>>>>	2 mR/hr	2000 dpm/100 sq cm

Room Released: Date: 3/23/05 Time: 12:30

Performed by:

Tod H. Richards 3/23/05
Date