



St Josephs
HOSPITAL • MILWAUKEE

5000 West Chambers Street • Milwaukee, WI 53210-1688 • 414/447-2000

Sumner

January 17, 1994

B. J. Holt, Chief
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Reply to a Notice of Violation
License #48-00537-03
Docket #030-03406
Dated December 30, 1993

Dear Ms. Holt:

As discovered during the NRC inspection of December 7, 1993, bioassays on some personnel present during I-131 administration were missing for the dates February 5, 1993; March 22, 1993; and September 15, 1993. A search for those records after the inspection failed to produce any documentation that these bioassays were conducted.

It was learned during the investigation of these events that a common condition was present in all three incidences. All three of these administrations occurred during the absence of the Nuclear Medicine Supervisor. The Supervisor has facilitated all I-131 administrations in the past. Failure to comply fully to all NRC regulations was due to the lack of experience on the part of Nuclear Medicine personnel engaged in the I-131 administration procedures during the supervisors absence.

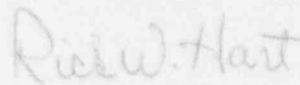
Iodine administration that requires hospitalization is not a high volume procedure, therefore, several Nuclear Medicine Technologists have not been fully involved in the application of this therapy. To resolve this problem, an all encompassing check list has been developed to allow any Nuclear Medicine Technologist or physician to fully comply with all NRC regulations pertaining to this procedure and the final acknowledgment of compliance will be the signature of the RSO on the check list form. A copy of this check list is enclosed for your review.

9402160028 940208
PDR ADOCK 03003406
C PDR

Although an I-131 administration has not taken place since the inspection, this check list procedure is in place and will be used at the next administration.

Also discovered during the NRC inspection was the failure to post a sign for the amount of time necessary to evacuate the Hot Lab Room (W173A) or the Lung Imaging Room (W173) in the event of an accidental spill of xenon gas. A review of the NRC license application did indeed contain an emergency procedure with the calculated time for evacuation of these rooms. The lack of a posted sign was an omission on our part. As calculated in the application dated May 31, 1985, a sign has now been posted with the emergency procedure to follow in the event of a spill, and the amount of time for the evacuation of these rooms. A copy of this signage is included for your review.

Sincerely,



Rick W. Hart
Vice President,
Professional and Support Services

RWH/dlw

ST. JOSEPH HOSPITAL

NUCLEAR MEDICINE DEPARTMENT

MILWAUKEE, WISCONSIN

January 14, 1994

Form: Safety Check List

THYROID ABLAT

Author___: RLO

Date Written___: 01-11-1994

Date Revised___: 01-14-1994

Safety Check List For Thyroid Ablation:

Name of patient: _____

NOTIFICATION OF PERSONNEL-

- 1) Notify 6 West nursing unit with the name of the patient and the date of the admission.
- 2) Notify the RSD and Oncology Dosimetry for film badges to 6 West.EXT 2221.
- 3) Instruct the patient to arrive early in AM; 0900-1000hrs.

PAPERWORK TO PREPARE-

- I-131 prescription form (Radioiodine Administration) with the amount to order signed by an authorized user. This should be done as soon as a thyroid ablation patient is known.
- Order the I-131 dose at least 24 hours in advance from the Nuclear Pharmacy.
- Hospital Authorization and Consent to Operation/Procedure form.
- Nursing Instructions for Patients Treated with I-131, P-32, or Gold-198 form (this form will be posted on the patient's door).
- Room radiation survey form (to be used at discharge) to document approval to release the room to the general public.
- Have the Radiology Secretary type the nuclear physician's orders onto a hospital order form. Do this prior to admission so the orders may go to the floor as soon as the patient is admitted.
- A "Caution Radioactive Materials" sign. (to be posted on the door).
- A "No Housekeeping, No Labs" sign. (to be posted on the door).
- The patient is to sign all forms prior to the administration of I-131.

ROOM PREPARATION-

ST. JOSEPH HOSPITAL

NUCLEAR MEDICINE DEPARTMENT

MILWAUKEE, WISCONSIN

January 14, 1994

Form: Safety Check List

THYROID ABLAT

Author___: RLO

Date Written___: 01-11-1994

Date Revised___: 01-14-1994

- Schedule a private room with private sanitary facilities.
- Cover all surfaces the patient will touch with absorbent paper and tape into place with masking tape. This includes a walkway from the bed to the toilet room and the entire toilet room floor, patient chairs, bedside table, vanity surface, and the shelves in the toilet room. Cover the "nurse call" hand control and telephone mouthpiece with plastic wrap. Do these things while the patient is in the room to explain what the paper is all about and to elicit the patient's cooperation.
- Explain to the patient about toilet habits, flush three times after each use, and wash their hands well.
- All food and beverages should be served with disposable tableware. DO NOT allow a non-disposable serving tray into the room.
- Cover the bed with disposable sheets and pillow cases.
- DO NOT allow the patient to wear their own bed clothing unless the patient is willing to leave their bed clothing in the hospital for decay-in-storage after discharge.
- Hang in the toilet room a plastic bag for the disposal of linens and a separate plastic bag for the disposal of food containers. Flush all unused food stuffs and unused beverages down the toilet before placing the containers into the plastic bag. CAUTION: Food stuffs must not plug the toilet.
- Measure and place a "visitor" line with tape on the floor at least 2 meters from the patient. Visitors will not be allowed into the room past this line. Non-pregnant visitors over the age of eighteen may visit for 30 minutes per day. NO OTHER VISITORS ARE PERMITTED.
- brief the nursing staff about the posted signs and nursing instructions concerning radiation safety.
- The radiation oncology dosimetrist will supply radiation badges to the nurses. EXT. 2221 (Laura).

DOSE ADMINISTRATION-

- Clear the room of all unneeded personnel.
- Record the names of all persons present at the administration:

ST. JOSEPH HOSPITAL

NUCLEAR MEDICINE DEPARTMENT

MILWAUKEE, WISCONSIN

January 14, 1994

Form: Safety Check List

THYROID ABLAT

Author___: RLD Date Written___: 01-11-1994 Date Revised___: 01-14-1994

Name: _____

Name: _____

Include the person who assayed the dose. These personnel will need a bioassay to determine their thyroid burden from I-131 within three days after the administration. (10CFR 35.315(a)(8) for compliance to 10CFR 35.75.

- Brief the patient about the clinical procedure.
- Administer the dose.
- Measure the dose rates at bedside, 1 meter from bedside (with the patient standing facing the survey meter) measure at the level of the umbilicus, the "visitor's safe line", in the hall with the door closed, and through the wall of the room next door. Record this information on the Nursing Instructions Sheet posted on the patient's door.

FOLLOWUP-

- Measure the dose rates as above until the patient (standing at one meter) measures $< 5\text{mR/hr}$. The patient may then have a whole body scan and neck uptake measurement.
- Discharge the patient.
- Collect waste and trash from the room, monitor and decay-in-storage those items or trash that measure above background.
- Record area monitoring with a survey meter after all the trash and paper on the floor and surfaces has been removed.
- Record the results of the wipe tests as per the room diagram. When all areas record at 200 dpm/cm² or less, release the room to housekeeping and the nursing unit. Remove all posted signs on the door from the therapy and post the Radiation Monitoring Report. Also, present one Radiation Monitoring Report to the unit secretary.

Therapy is completed in compliance with NRC regulations.

RSO

Date

12/09/93

* XENON SPILL *

In the event of an accidental release of 10mCi of xenon-133, close all outside doors to W173 and W173A. Leave the door to the HOT LAB between W173 and W173A open.

Vacate room W173 and W173A for ONE HOUR.

Post a sign on the outside of all doors to W173 and W173A with what time it is permissible to use the rooms again.