

License Number 53-05379-01 Report No. 030-03546/89-01

October 4, 1989

Regional Administrator
U.S. Nuclear Regulatory Commission, Region V
1450 Maria Lane, Suite 210
Walnut Creek, California 94596

ATTENTION:

Document Control Desk. Washington, D.C. 20555

SUBJECT:

Reply To Notice Of Viclation

Centlemen:

This is in response to your letter dated September 14, 1989 on NRC inspection and notice of violation to Kaiser Foundation Hospital, Honolulu, Hawaii. The reply is as follows:

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10 CFR 20.401(a) requires in part that each licensee maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required.

Contrary to the above requirement, the licensee did not maintain a record showing the radiation exposure of a person who remained in the room of a radiation therapy patient between April 4 and April 7, 1989, and for whom personnel monitoring was required.

REASON FOR VIOLATION: This is the special circumstances which was described earlier in your detailed report of inspection and on my letter written to NRC, Region V on August 24, 1989. The patient's wife was allowed to stry with the patient to do tracheal suction during the course of radiation therapy. She was given a film badge but the badge was lost. This loss of the film badge was due to inadequate follow up; probably did not collect film badge to be processed.

CORRECTIVE ACTION: In the future, when there are special circumstances similar to this incident, physicist consultant will be consulted, a special Radiation Safety Committee meeting will be called to consider and approve the procedure. We may

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call NRC for recommendation and approval. There will be more thorough follow up on the film badge reading on the person who may receive higher radiation than usual, such as this patient's wife.

DATE OF COMPLIANCE: Imrediately.

VIOLATION B

10 CFR 20.201(b) requires that each license make or cause to be made such surveys or evaluations as may be necessary for the licensee to comply with the regulations in this part, and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present.

Contrary to the above requirement, at the time of the inspection, the licensee had not completed an evaluation of two lost personnel monitoring devices to estimate the dose recorded on the devices during October 1987 and December 1988.

REASON FOR VIOLATION: In the past, we recorded the lost film badge and investigated whether the personnel may have received any higher radiation than usual or not during the period that the lost film badge covered. It was not known to us that we needed to calculate estimated dose in numerical figures for every lost film badge.

Please note that one of the film badges that was thought to have been lost in October 1987 was found and must have been turned in by another individual (see Attachment A).

CORRECTIVE ACTION: Beginning immediately, the lost film badge will be reported by personnel and investigated. The estimated radiation exposure during that period will be calculated by considering the previous exposure record. The estimated dose will be sent to Radiation Detection Company to be included in the personnel lifetime record. New SOP was made (please see Attachments B, C, D & E).

DATE OF COMPLIANCE: Immediately.

VIOLATION C

10 CFR 35.60(b) requires each licensee to conspicuously label each syringe or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name, clinical procedure to be performed, or the patient's name.

Contrary to the above requirement, at the time of the inspection, the licensee was not labelling syringes or syringe radiation shields.

REASON FOR VIOLATION: The syringe shields were not consistently labeled because of oversight on the regulation.

CCRRECTIVE ACTION: The syringe shield will be labeled with color-coded labeling of radiopharmaceuticals (see Attachments F & G). Each color code will be for the radiopharmacutical and name of examination.

DATE OF COMPLIANCE: Immediately.

C1 the subject of NRC concern regarding Decha Intaraprasong, M.D., who is now both Radiation Safety Officer and Chairman of Radiation Safety Committee. Starting immediately, Peter Clapp, M.D., Radiologist, is appointed as Chairman of Radiation Safety Committee and Dr. Decha Intaraprasong will remain Radiation Safety Officer.

Sincerely,

Ronald Mikolajczyk

Administrator

Decha Intaraprasong, M.D. Radiation Safety Officer

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Anna Mikelyjik

KAISER FOUNDATION HOSPIT L 'N DEPT OF RADIOLOGY 3298 MOANALUA ROAD HONOLULU HI 96819

ATTACHMENT

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DOCIMETRY REPORT

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ATTACHMENT B

LOST/DAMAGED BADGE REPORT

LOST/LAMAGED (CI	ROLE OND) PERIOD: // to //
DEPARTMENT:	
	'DANAGLD? :
PADIATION:	E DUTTES THAT HAVE TO DO WITH YOUR ROUTINE USE OF
YOU TO BELIEVE T	CTIVITIES DURING THE LOST/DAMAGED PERIOD WOULD LEAD THAT YOUR RADIATION EXPOSURE WOULD BE MORE OR LESS
PLEASE RETURN T	O THE RADIATION SAFETY OFFICER. THANK YOU.

REPORT OF LOST FILM BADGE AND ESTIMATE OF WHOLE BODY EXPOSURE

SUMMARY OF DATA:	
Worker:	SSN:
Institution:	
Dosimeter Interval:	
Estimated Exposure:	
DESCRIPTION:	
investigation, it was deevents during this month we than normal whole body exposure records for the following the lost dosime per month. Therefore, a mrem should by ass	d to determine the types and quantities during that month. During the termined that there were no unusual hich would have accounted for a higher exposure. Review of this worker's three months prior and three months ter revealed an average of mrem whole body exposure of approximately igned to this worker for the month of ords updated accordingly.
SUBMITTED BY:	DATE.



Date:

Radiation Detection Company 162 Wolfe Road P.C. Box 1414 Sunnyvale, CA 94088

RE: Lost Film Badge Report

To wnom It May Concern:

The folloging employee has lost:

Film badge______Ring badge_____

Name: SSN: Acct #: Group #: IBM #: Time Period: Estimated Radiation Exposure:

Please include estimated radiation exposure in the employee's record.

Sincerely,

Decha Intaraprasong, M.D. Radiation Safety Officer

STANDARD OPERATING PROCEDURE

Diagnostic Imaging Department Moanalua Medical Center

POLICY: Lost radiation badges shall be reported by the user to their supervisor. The Supervisor shall submit the report to the Radiation Safety Officer.

Personnel included in these procedures:

- Authorized users of radioisotope who are required by NRC to wear film badge (body or ring badge).
- 2. Nuclear medicine technologists.
- 3. Nurses who are certified to three for I131 therapy patients.
- 4. Opnthalmology personnel who use or help in Sr^{90} eye applicator therapy.

PROCEDURE:

RADIATION WORKERS

- Report immediately to supervisor or Radiation Safety Officer of the incident.
- Complete the lost film badge form and send to Supervisor
 - The form can be obtained from Nuclear Medicine.

SUPERVISOR

- Send the lost film badge report to RSO.
- Monthly or quarterly, where applicable, audit the film badge reading record.
- Investigate the personnel who are required to wear film badges but have no reading record.
 - 5.1 Reconfirm with personnel whether film badge is lost.

Diagnostic Imaging Department

TITLE: LOST FILM BADGE REPORTING REV:

5.1.1 If film badge was lost, have the personnel complete the form, then send to RSO.

RSO OR DESIGNEE

- Investigate the lost film badge incident.
 - Calculate in numerical figure the estimated radiation exposure the personnel could have received during that period using the past expose record.
- 8. Send the estimated dose to the Radiation Detection Company to be included in the employee's litetime record.

STANDARD OPERATING PROCEDURE

Diagnostic Imaging Department Moanalua Medical Center

SUBJECT: NUCLEAR MEDICINE PROC: 1452-N32
DATE: 11/88
TITLE: RECEIPT AND ACCOUNTABILITY OF REV: 9/89
RADIOPHARMACEUTICALS

Upon receipt of pharmaceuticals daily from the Pacific Radiopharmacy, the following procedure will be utilized.

NUCLEAR MEDICINE TECHNOLOGIST

- Monitors the shipment at the surface and at one meter using the Picker Survey meter, model 655-186 and the correct settings. Records these reading's as MR/HR on the bottom of the pharmacy log sheet. (see example, letter A).
- Checks the pharmaceutical inventory against the packing list and the patient list to insure all ordered pharmaceuticals are present.
- Records purchase number on the packing list and signs full signature at the bottom of the packing list. Files packing list.
- 4. Performs wipe tests using a Q-tip applicator and Victoreen 493 Pancake Probe.
 - 4.1 The read container, top and bottom, as well as the sides and bottom of the vial itself must be wiped and monitored.
- Records these readings as counts per/100cm²
 on the bottom of the pharmacy log sheet.
 (This reading should not exceed 100 cts/100cm²). (see example, letter B).
- Places labels on the pharmacy log sheet with allowance for proper number of patients.
- Assays vial on proper isotope setting to determine current activity and concentration.

Diagnostic Imaging Department

SUBJECT: NUCLEAR MEDICINE

PROC: 1452-N32 DATE: 11/88

TITLE: RECEIPT AND ACCOUNTABILITY OF

RADIOPHARMACEUTICALS

REV: 9/89



Records on pharmacy log sheet next to the 8. proper label the time of assay, the total volume off the label, the total activity, and the activity per milliliter. (see example, letter C).

NUCLEAR MEDICINE TECHNOLOGIST

- 9. As each individual patient dose is prepared, the previous assay is decayed to the present time utilizing the proper decay factor. The desired patient dose is divided by the current assay to determine the amount of solution to be withdrawn for the patient dose.
- Using proper sterile technique, withdraws the 10. dose and places it in the dose calibrator well.
- Insuring that the proper dose calibrator 11. isotope button or setting has been used. Records the dose on the pharmacy log sheet under the proper isotope label.
 - 11.1 This includes patient's name, medical record number, time of preparation, assay at the time of preparation, the total activity of the patient dose, the amount of solution withdrawn to prepare the dose, the consecutive number withdrawn from the product, the type of study to be performed, and the initials of the preparer.
- Records the proper radiopharmaceutical and 12. total activity on the patient requisition.
- Places the dose in a proper syringe shield for injection.
- Affixes the proper color coded label to the 14. syringe, requisition and pharmacy log sheet for the dose, patient and procedure being performed. (see procedure 1452-N32-01).

Diagnostic Imaging Department

SUBJECT: NUCLEAR MEDICINE PROC: 1452-N32 DATE: 11/88

TITLE: RECEIPT AND ACCOUNTABILITY OF REV: 9/89 RADIOPHARMACEUTICALS

IN CHARGE

RADIOLOGIST 15. Reviews and signs the pharmacy logsheets weekly.

> 15.1 The white copy is maintained on file in the department and the vellow copy is sent to the Pacific Radiopharmacy for billing purposes.

STANDARD OPERATING PROCEDURE

Diagnostic Imaging Department Moanalua Medical Center

SUBJECT: NUCLEAR MEDICINE PROC: 1452-N32-01

----- DATE: 9/89

TITLE: COLOR-CODED LABELING OF RADIO- REV:

PHARMACEUTICALS

- Each dose prepared for Nuclear Medicine will have a uniquely numbered, color-coded label assigned and affixed to the syringe, radiopharmacy log and the patient requisition.
- 2. Prior to injection, the technologist will verify that the number and color of the label on the syringe matches the number and color of the label on the patient requisition. The technologist will also verify that the color properly designates the correct radiopharmaceutical that is required for the indicated procedure.
- In the event of any discrepancy, discard the dose and prepare a proper dose.
- 4. The current color code is:

Red - Technetium 99m Medronate Diphosphonate - Bone Scan

Green - Technetium 99m Pertechnetate - Brain Scan Meckel's Diverticulum Thyroid

Yellow - Technetium 99m Sulfer Colloid - Liver Spleen acan

Pumpkin - Technetium 99m Disofenin - Biliary Scan

White - All others

5. Color code will be posted in the isotope preparation room.