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PDR

JUN 16 1994

Docket: 030-03546
License: 53-05379-01

Kaiser Foundation Hospital
ATTN: Dee Jay Mailer
Regional Hospital Administrator
3288 Moanalua Road
Honolulu, Hawaii 96819

SUBJECT: NRC INSPECTION REPORT 030-03536/94-01

Thank you for your letter of May 24, 1994, in response to our letter and Notice of Violation dated May 4, 1994. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. In paragraph A. (2) you stated in part that, "all nuclear medicine technologists were instructed ... that the dosage record must reflect the final actual dosage administered to each patient." Based on a telephone conversation on June 14, 1994, between your Radiation Safety Officer, Mr. P. Manly and Mr. G. Yuhas of my staff we understand that the technologists were instructed to record the actual volume injected as a part of the dosage record. We will review the implementation of your corrective actions during a future inspection to determine that full compliance has been achieved and will be maintained.

Sincerely,
Original signed by
F. A. Wenslawski, Chief
Materials Branch
Division of Radiation Safety
and Safeguards

cc:
State of Hawaii

bcc:
DMB - Original (IE-07)
LJCallan
SJCollins
RAScarano
DWeiss, OC/LFDCB (T-9E10)
WLFisher
CLCain
FAWenslawski
Inspector
NMIB
MIS System
WCFO Files (2)

WCFO	C:MLB	DCS
GYuhas GPY	FAWenslawski	Yes/No
6/15/94	6/15/94	

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KAISER PERMANENTE

Reply to a Notice of Violation

May 24, 1994

Regional Administrator
U. S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

Docket No. 030-03546
License No. 53-05379-01
Inspection Report No. 030-3546/94-01

Pursuant to the provisions of 10 CFR 2.201, Kaiser Foundation Hospital is submitting this written response to a NOTICE OF VIOLATION dated May 4, 1994.

A. 10 CFR Part 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the written radiation safety procedures and quality management procedures established by the licensee.

(1) The reason for the violation: The nuclear medicine technologist calculated the volume of phosphorus-32 that contained the prescribed activity based on the radiopharmaceutical label and recorded the volume in the radiopharmaceutical dosage log. He then drew up the initial volume of phosphorus-32 and assayed it in the dose calibrator. When the dose calibrator reading indicated the dosage was not within 10% of the prescribed dosage, he altered the volume and reassayed the dosage. He failed to revise the radiopharmaceutical dosage log record to read the final volume of the phosphorus-32 dosage actually administered to the patient.

(2) The immediate corrective steps taken: Upon discovery of the fact that the nuclear medicine technologist failed to record the actual final volume of each dosage in cases when the initial dosage drawn is adjusted, all nuclear medicine technologists were instructed at the Nuclear Medicine staff meeting on March 17, 1994 of the requirement that the dosage record must reflect the final actual dosage administered to each patient.

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Kaiser Foundation Hospital
3288 Moanalua Road Honolulu HI 96819 (808) 834-5535

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(3) The corrective steps taken to prevent recurrence: All nuclear medicine technologists were retrained in the proper procedure for calculating and recording dosages administered to patients. The training included the procedure for determining the dosage to be drawn of pure beta emitting radionuclides. The Nuclear Medicine Chief Technologist Administrator, authorized physician users, RSO and the consulting auditor will increase their oversight of the nuclear medicine technologists' performance to identify deviations from written radiation safety and quality management procedures.

(4) The date when full compliance was achieved: Full compliance was achieved on March 17, 1994.

B. 10 CFR Part 35.21(a) requires, in part, that a licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program to ensure that the radiation safety activities are being performed in accordance with regulatory and license requirements in the daily operation of the licensee's byproduct material program.

(1) The reason for the violation: The institution's management failed to recognize that the RSO had not implemented the revised procedures which established an inventory record of byproduct material and incorporated the other requirements of 10 CFR Part 20.1001-2401 and to review activities and sign documents generated by the radiation safety program in a timely manner.

(2) The immediate corrective steps taken: Management performed a review of the tasks delegated to the RSO and the expertise and time required to accomplish the tasks. Since the physician designated as the RSO did not feel qualified to perform the radiation safety duties required of the RSO, her resignation was accepted on March 14, 1994. An interim RSO, Philip J. Manly, who is a certified health physicist with the expertise to perform the radiation safety duties, was appointed on March 15, 1994. The appointment of Mr. Manly as permanent RSO was subsequently approved by the Radiation Safety Committee and by the NRC in the materials license Amendment No.45.

(3) The corrective steps taken to prevent recurrence: The consulting contract between the Kaiser Foundation Hospital and the new RSO, Philip J. Manly, CHP, was amended to allow for the amount of time on site identified in the management review that is needed to ensure adequate oversight of the

radiation safety program. Using the review document, management will track the performance of the RSO.

(4) The date when full compliance was achieved: Full compliance was achieved on May 12, 1994.

Submitted by:

Kaiser Foundation Hospital

Dee Jay Mailer

Dee Jay Mailer
Regional Hospital Administrator

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

Docket File

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

MAY 4 1994

Docket No.: 030-03546
License No.: 53-05379-01

Kaiser Foundation Hospital
3288 Moanalua Frontage Road
Honolulu, Hawaii 96819

Attention: Dee Jay Mailer
Regional Hospital Administrator

SUBJECT: NOTICE OF VIOLATION
NRC INSPECTION REPORT NO. 030-03546/94-01

This refers to the inspection conducted by John Jacobson of this office on February 28, March 1-3, 21, April 1, 4, and 7, 1994. The inspection included a review of the circumstances surrounding four injections of phosphorous-32 (P-32) in 1992 reported by you to NRC on February 10, 1994, to be misadministrations and a review of your Radiation Safety Officer's (RSO) oversight and implementation of activities authorized for the use of radioactive materials under your NRC license. At the conclusion of the inspection, the inspection findings were discussed with you and members of your staff.

The inspection was an examination of the activities conducted under your license as they relate to radiation safety, and to compliance with the Commission's rules and regulations. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observation of activities in progress.

Based on the results of this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice). These items have been categorized by severity levels as described in the NRC Enforcement Policy, 10 CFR Part 2, Appendix C. The violations are of concern because they were identified by the NRC and because they indicate a weakness in certain areas of your radiation safety program and the RSO's oversight of that program.

The NRC inspection of the circumstances surrounding the events reported as misadministrations indicated that two of the four events were not misadministrations, but were reported as such because of incorrect volumes recorded in your radiopharmaceutical dose logs. A analysis of the accuracy of your dose calibrator for assaying P-32 doses performed by your interim RSO subsequent to the on-site inspection indicates that the other two events also were not misadministrations. Based on the inspection and review of the information provided on P-32 accuracy detailed in letters dated March 31, April 1, and April 15, 1994, the NRC has no basis for challenging your conclusion that these events were not misadministrations, as you have since reported to the patients involved. The case demonstrates how important a

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thorough investigation of events such as these can be to ensure that proper reports are made initially.

The inspection of the events reported as misadministrations was complicated by incorrect data recorded in your dose logs. The violation of 10 CFR 35.25(a)(2) for the failure of nuclear medicine technologists to record the actual volume withdrawn from vials to prepare doses made it difficult to reconstruct the actual doses delivered to certain of the patients involved to determine if misadministrations had occurred, and thus was categorized as a Severity Level IV violation. The violation underscores the importance of ensuring that supervised individuals are instructed in and follow licensee written procedures and recordkeeping requirements as opposed to standard industry practices. An NRC medical consultant also reviewed the events reported as misadministrations and concluded that the impact of the events on the health of the patients was negligible.

The violation of 10 CFR 35.21 for failure of the RSO to implement revised procedures incorporating the requirements of the Revised Part 20 and to establish an inventory procedure was indicative of the lack of regular oversight provided by the RSO at your facility because of insufficient time and training. Hospital management should continue to evaluate the amount of time devoted to the program by the new RSO and the level of his involvement in the program.

A violation of 10 CFR 35.32(d)(1) for failure to retain a written directive for three years was identified by your consultant during a quarterly audit. A violation of 10 CFR 35.32(a)(1) for failure to include the radioisotope and treatment site in strontium-90 (Sr-90) eye applicator written directives was identified by the inspector. However, these violations are not being cited because of your prompt corrective action to ensure all written directives are retained and prompt commitment to amend your procedures to include all the information required for Sr-90 brachytherapy written directives, and because the enforcement discretion criteria specified in Section VII.B of the Enforcement Policy (10 CFR Part 2, Appendix C) were satisfied. Your attention is called to NRC Information Notice 94-17, entitled "STRONTIUM-90 EYE APPLICATORS: SUBMISSION OF QUALITY MANAGEMENT PLAN (QMP), CALIBRATION, AND USE," issued on March 11, 1994.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

NOTICE OF VIOLATION

Kaiser Foundation Hospital
3288 Moanalua Frontage Road
Honolulu, Hawaii 96819

Docket No. 030-03546
License No. 53-05379-01

During an NRC inspection conducted on February 28, March 1-3, 21, April 1, 4, and 7, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

A. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the written radiation safety procedures and quality management procedures established by the licensee.

Procedure Number 1452-N32 of the licensee's Diagnostic Imaging Standard Procedures, entitled "Receipt and Accountability of Radiopharmaceuticals," dated January, 1992, states in Item 11, in part, that the nuclear medicine technologist records the dose on the pharmacy log sheet under the proper isotope label. Subitem 11.1 states, in part, that this includes the amount of solution withdrawn to prepare the dose.

Contrary to the above, on March 9, 1992, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, failed to record the actual amount of solution withdrawn to prepare a therapy dose of beta-emitting phosphorous-32 (byproduct material) on the licensee's pharmacy log sheet. Furthermore, as of February 28, 1994, nuclear medicine technologists routinely failed to record the actual volume withdrawn to prepare doses of byproduct material.

This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 35.21(a) requires, in part, that a licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program to ensure that radiation safety activities are being performed in accordance with regulatory and license requirements in the daily operation of the licensee's byproduct material program. 10 CFR 35.21(b) requires, in part, that the Radiation Safety Officer shall establish and implement written procedures for the radiation safety program, including a procedure for keeping an inventory record of byproduct material.

Contrary to the above, as of March 1, 1994, the licensee, through its Radiation Safety Officer, failed to implement revised procedures which incorporate the requirements of 10 CFR 20.1001-2401 (Revised Part 20, "Standards for Protection Against Radiation," effective January 1, 1994) to establish a procedure for keeping an inventory record of byproduct material, and the RSO failed to ensure that radiation safety activities are being performed in accordance with regulatory and license requirements in the daily operation of the licensee's byproduct material program.