DEPARTMENT OF VETERANS AFFAIRS
Carl T Hayden Medical Center
650 East Indian School Road
Phoenix AZ 85012

MAY 27 1994

In Reply Refer To: 644/114

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

Dear Sir:

This is in reply to your letter dated April 21, 1994, subject; Reply to Notice of Violation, Docket No. 030-01209, License No. 02-10072-01. The following information is provided per your request:

10 CFR 35.32(d) requires, for each administration of a radiopharmaceutical or radiation for which a written directive is required under 10 CFR 35.32(a)(1), that the licensee retain, for three years after the date of the administration, the written directive and a record of the radiation dose or radiopharmaceutical dosage administered.

10 CFR 35.32(a)(1) requires that, prior to administration, a written directive be prepared for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

Contrary to the above, between April 1, 1992, and November 5, 1993, the licensee administered I-131 in quantities between 80 microcuries and 15.6 millicuries and, as of March 23, 1994, the licensee did not maintain the written directives.

Not Contested

Action:

. Compliance has been immediate as of the date of inspection. All written directives prepared under our quality management program for administration of quantities of I-131 or I-125 greater than 30 microcuries are being maintained in the Department of Nuclear Medicine.

. A copy of SF Form 519 (Radiologic/Nuclear Medicine Consultation Form), identifying patient, procedure to be performed and signature of requesting provider, is also kept with the same written directive.

10 CFR 35.32(e) provides that the licensee may make modifications to the quality management program to increase the program's efficiency and requires that the licensee furnish the modification to the appropriate NRC Regional Office within 30 days after the modification had been made.

Contrary to the above, the licensee modified its quality management program by changing the checklist form and associated procedure in April 1992, and did not furnish a copy of the modification to the NRC.

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Not Contested

. The initial directive for administration of I-131 in quantities greater than 30 microcuries (quality management checklist) was submitted to the NRC on December 20, 1991, for its approval, although, at that time, there was some confusion as to whether the required directive pertained to both diagnostic and therapeutic doses or just to therapeutic quantities. However, while waiting for NRC's response, the initial directive was revised and, consequently, the NRC was not furnished the notice of modification of the initial directive.

Action:

. The modified directive for administration of either I-131 or I-125 in quantities greater than 30 microcuries, which is more stringent than the initial directive, will be submitted to the NRC no later than May 31, 1994.

. We will continue to maintain this written directive in the Nuclear Medicine Department for any administration of quantities greater than 30 microcuries of either I-131 or I-125.

. All written directives that are prepared under our quality management program are to be reviewed by the Radiation Safety Officer (RSO) on a quarterly basis and be reported to the Radiation Safety Committee (RSC) at the same time interval.

. An educational process has been implemented for the authorized users and the technologists concerning the said quality management program and the written directive with proper documentation of that training.

10 CFR 35.205(e) requires, in part, that a licensee check each month the operation of reusable collection systems for radioactive gases.

Contrary to the above, the licensee used a reusable collection system for radioactive xenon-133 gas and did not check the operation of the collection system at monthly intervals from May 1991 to February 1994.

Not Contested

Action:

. Operation of the reusable collection system for radioactive xenon-133 gas will be monitored at monthly intervals.

. Full compliance is expected no later than May 15, 1994.

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10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for use of protective clothing and for conducting personnel monitoring applicable to using radiopharmaceuticals are described in Appendix I to Regulatory Guide 10.8, Revision 2, which was included as part of the application dated July 13, 1990, and approved by License Condition No. 14.A.

Item 1, Appendix I to Regulatory Guide 10.8, enclosed with the application dated July 13, 1990, requires that laboratory coats or other protective clothing be worn at all times in areas where radioactive materials are used. Item 3, of Appendix I requires that personnel monitor their hands for contamination in a low-background area after each procedure using radioactive material or before leaving the area.

Contrary to the above, on March 16-17, 1994, the licensee, through its Radiation Safety Officer, failed to ensure that licensed activities were being performed in accordance with the above procedures. Specifically, a radiation worker did not wear a laboratory coat or other protective clothing at all times in the Nuclear Medicine Laboratory where radioactive materials were used, and the worker did not monitor his hands after each diagnostic imaging procedure or before leaving the Laboratory.

Not Contested

Action:

. Compliance has been immediate as of the inspection date: Lab coats are worn by the nuclear medicine personnel in the areas where radioactive materials are used. Also, the technologists monitor their hands before leaving the Nuclear Medicine Department. These items will be subject to periodic survey by the Radiation Safety Officer and will be documented as such.

10 CFR 20.1906(b) and (c) require that each licensee monitor the external surface of a package labeled with a Radioactive White I, Yellow II, or Yellow III labels for radioactive contamination and radiation levels not later than three hours after receipt of the package during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

Contrary to the above, on multiple occasions between January 1 and March 23, 1994, the licensee received packages labeled with either White I, Yellow II and Yellow III labels, and the licensee did not monitor the packages for radioactive contamination.

Not Contested

Action:

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. The external surface of all labeled packages will be monitored for radioactive contamination and radiation level, utilizing a ludlum probe capable of counting 2000 < DPM. In case of radioactive contamination, the contracting radiopharmaceutical company and the Radiation Safety Officer (RSO) will be notified. Full compliance is expected upon receipt of the probe on or about early July 1994.

. Additionally, we will continue visual inspection of all "packages" as stated in our license (attachment 10.7-A)

Management Improvement Plan

The written quality management program concerning administration of I-131 and I-125 in quantities greater than 30 microcuries is to be revised to specify:

. Mandatory requirement for a written directive listing elements to be included in such a directive.

. All written directives shall be reviewed, verified and properly signed by the authorized users.

. All written directives shall be retained in the Nuclear Medicine Department for three (3) years after the date of administration.

The Radiation Safety Officer (RSO) or Chief, Nuclear Medicine Section*, shall survey the patient care activities in the Nuclear Medicine Department including:

. Periodic audit (monthly, quarterly, semiannually and annually) of the quality control/radiation safety checklist program, with monthly and quarterly reporting to the Radiology Service Administrative Professional Meeting and the Radiation Safety Committee, respectively.

. Quarterly audit of the quality management program for administration of I-131 and I-125 with reporting to the Radiation Safety Committee at the same time interval.

* In the absence of the RSO, coverage is to be provided by the Chief, Nuclear Medicine Section.

The monitoring results are profiled to determine if a problem exists. Peer review and focus study are carried out to identify cause(s) of any problem and methods by which process/performance can be improved. When a problem is identified, corrective action is taken for resolution of the identified deficiency.

However, if the needed action exceeds the authority of the Radiology Management, the matter is referred to the Clinical Executive Board for solution/further action.

Sincerely yours,

JOHN R. FEARS
Medical Center Director

cc: Regional Administrator, Region IV

NRC, Walnut Creek Field Office