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

February 26, 1997

Wm. Ted Galey, M.D., Chief Executive Officer
Department of Veterans Affairs
Medical Center
P.O. Box 1034
3710 S.W. U.S. Veterans Hospital Road
Portland, Oregon 97207

SUBJECT: NRC INSPECTION REPORT 030-02935/97-01 AND NOTICE OF VIOLATION

Dear Mr. Galey, M.D.:

On January 7-10, 1997, the NRC conducted a special announced inspection at the Department of Veterans Affairs Medical Center, Portland, Oregon. The inspection was conducted in response to a radiopharmaceutical misadministration that occurred at your facility on December 18, 1996. The findings of the inspection were discussed with you and other members of your staff during an interim exit briefing on January 10, 1997, and during a telephonic exit briefing on January 31, 1997. Discussions relative to the inspection were also held with the radiation safety officer on January 24, 1997.

The inspection included a review of the events leading to the misadministration and direct, contributing, and root causes of the misadministration. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel and direct observation of licensed activities. Specific areas reviewed during the inspection are discussed in detail in the enclosed Inspection Report 030-02935/97-01.

Based on the results of this inspection, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and involved failures to: (1) prepare a written directive for the administration of a dosage containing 320 microcuries of sodium iodide I-131 during a thyroid uptake measurement; and (2) notify a patient or responsible relative (or guardian) of a misadministration within 24 hours after its discovery.

The misadministration occurred because of the failure to verify the prescribed I-131 dosage prior to its administration by obtaining verbal approval or written directive authorization from the nuclear medicine physician staff. Although the amount of the dose administered was small, had no adverse health effect, and represented an isolated occurrence, the failure to follow your quality management program previously established to help prevent such errors is a significant omission and concern.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO

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DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Should you have any questions concerning this inspection, please contact Mr. David D. Skov at (510) 975-0253.

Sincerely,

Ross A. Scarano, Director
Division of Nuclear Materials Safety

Docket No.: 030-02935
License No.: 36-01395-01

Enclosures:
1. Notice of Violation
2. NRC Inspection Report
   030-02935/97-01
3. NRC Information Notice 96-28

cc w/enclosures:
Oregon Radiation Program Control Director

Department of Veterans Affairs
National Health Physics Program (115HP)
ATTN: Dr. F. Herbig
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St. Louis, MO 63106

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