to the wrong patient will not be cited as a violation of 10 CFR 20.1301 in this case. Pending rulemaking to resolve the issue that 10 CFR Part 35 should be applied in such cases, the NRC will exercise discretion and will not issue citations for violations of 10 CFR 20.1301 caused by errors in the administration of radiation or radioactive material to patients.

Nevertheless, such an event clearly would have resulted in a misadministration if the dose to the patient had exceeded 5 rems total effective dose equivalent (TEDE) or 50 rems to any individual organ. Depending on the procedure in question, an administration of technetium-99m may result in such a dose. Moreover, two similar errors involving administrations of diagnostic radiopharmaceuticals to the wrong patient had occurred in the recent past at your facility. The NRC recognizes that, after the third event, you took prompt action to prevent a further recurrence. However, you should have taken more effective action following the previous events. Had you fully analyzed the root causes for the previous events, the third event, which is evidence of the further potential for a medical misadministration, could have been prevented. This matter, as well as the number and nature of the violations that are being cited, indicate the need for management to exercise increased oversight and control over licensed activities.

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. In addition, your response should describe actions taken or planned to improve management oversight and control of NRC-licensed activities. 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.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

L. J. Callan
Regional Administrator

Enclosures:
Notice of Violation
NRC Enforcement Conference Report 93-02

NOTICE OF VIOLATION

Veterans Affairs Medical Center
Long Beach, California

Docket No. 030-01215
License No. 04-00689-07
EA 93-203

During an NRC inspection conducted on July 19-23, and 30, 1993, 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 20.1801 requires in part that licensed materials stored in unrestricted areas be secured against unauthorized removal or access. As defined in 10 CFR 20.1003, an unrestricted area is an area access to which is neither limited nor controlled by the licensee.

Contrary to the above, on July 20, 1993, licensed material consisting of technetium-99m waste located in the Nuclear Medicine Treadmill Room, an unrestricted area, was not secured against unauthorized removal or unauthorized access; on July 22, 1993, licensed material consisting of tritium, carbon-14, sulfur-35, iodine-125, and phosphorus-32 located in the Research Building, was not secured against unauthorized removal or unauthorized access. (01014)

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

B. 10 CFR 35.60(c) requires in part that a licensee require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit.

Contrary to the above, on July 20, 1993, while preparing a radiopharmaceutical kit, the licensee's nuclear medicine technologist did not use a syringe shield for a syringe containing technetium-99m. (02014)

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

C. License Condition 18 requires in part that the licensee possess and use licensed material in accordance with the statements, representations, and procedures contained in the application dated June 6, 1991, and the letter dated November 15, 1991.

The licensee's application dated June 6, 1991, and the letter dated November 15, 1991, adopted the model procedures specified in Regulatory Guide 10.8, Revision 2, "Guide for Preparation of Applications for Medical Use Programs," as modified by the licensee, and Regulatory Guide 8.20, Revision 1, "Applications of Bioassay for Iodine-125 and Iodine-131," without modifications.

1. Regulatory Guide 10.8, Appendix I, Item 1 specifies that personnel wear laboratory coats or other protective clothing at all times while in areas where radioactive materials are used. This requirement was not modified by the licensee.

Contrary to the above, on July 20 and 22, 1993, five research and three nuclear medicine personnel failed to wear laboratory coats or other protective clothing while they were in areas where radioactive materials were used. (03014)

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

2. Regulatory Guide 10.8, Appendix I, Item 3, as modified by the licensee in Item 10.4 of the application dated June 6, 1991, recommends that personnel working in radioisotope use areas designated by the Radiation Safety Committee monitor their hands and feet with a radiation detection device before leaving the area or after each radioisotope procedure. The Nuclear Medicine Department has been designated as a radioisotope use area which requires monitoring of hands and feet.

   Contrary to the above, on July 20, 1993, nuclear medicine personnel who had been using radioisotopes left the area without monitoring their hands and feet. (04014)

   This is a repeat violation, second occurrence.

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

3. Regulatory Guide 10.8, Appendix I, Item 11, and Appendix N, Items 1.B and 1.C, specify in part that radiation and contamination surveys be performed weekly and monthly in areas where radioactive materials are stored or used, respectively. This requirement was not modified by the licensee.

   Contrary to the above, as of July 23, 1993, weekly surveys had not been performed in research laboratories 119, 120, 233, and 242, areas where radioactive material was stored. In addition, Laboratory 233, an area where radioactive material was being used, was not surveyed during April 1993; Laboratory 113, an area where radioactive material was being used, was not surveyed during July and December 1991, August, November, and December 1992, and February, April, and June 1993. (05014)

   This is a repeat violation, second occurrence.

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

D. License Condition 18 requires in part that the licensee possess and use licensed material in accordance with the statements, representations, and procedures contained in the letter dated November 15, 1991.

   Attachment 2 (VA Form 10-1152) of the letter dated November 15, 1991, states the maximum allowable possession limit for each

Principle Investigator authorized by the Radiation Safety Committee. VA Form 10-1152 for the Principle Investigator assigned to Room 233 specifies an allowable possession limit of 1.0 millicurie of tritiated glucosamine.

Contrary to the above, between October 23 and November 24, 1992, the total possession of tritiated glucosamine for the Principle Investigator in Room 233 was 1.31 millicuries, and between December 23, 1992 and February 8, 1993, the total possession of tritiated glucosamine was 1.395 millicuries. (06014)

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

E. 10 CFR 35.92(b) requires that a licensee retain for three years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a).

Contrary to the above, as of July 23, 1993, the licensee disposed of radioactive waste collected by custodial and nuclear medicine personnel but did not maintain a record of the disposals. (07014)

This is a repeat violation, second occurrence.

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

Pursuant to the provisions of 10 CFR 2.201, Veterans Affairs Medical Center, Long Beach, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington D.C. 20555, with a copy to the Regional Administrator, Region IV, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reasons for the violation, or, if contested, the basis for disputing the violations, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, the Commission may issue an Order or a Demand for Information as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Arlington, Texas
this 11th day of May 1994