Medical Center

1310 24th Avenue, South
Nashville TN 37212-2637

Veterans Administration

REPLY TO A NOTICE OF VIOLATION

November 27, 1990

In Reply Refer To: 626/115

Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

SUBJ: NRC Inspection Report No. 41-00104-04/90-01
Docket No. 030-03250

In response to your letter dated November 7, 1990 regarding the "NOTICE OF VIOLATION" of NRC regulations, the following corrective steps have been taken to bring this medical center in compliance with the regulations and conditions of our license:

A. License Condition No. 23 requires that licensed radioactive materials be possessed and used in accordance with the statements, representations and procedures contained in the radioactive material license application dated January 15, 1985 and in the documents in support of that application.

Item 15 of the application dated January 15, 1985 states the rules for the safe use of radioactive materials are established in Chapter 4 of the Radiation Safety Manual. Section 4.B.1, Page 4-4 of the manual states that protective gloves should be worn when radioactive contamination is possible.

The violation occurred due to an oversight by a nuclear medicine technologist. Retraining of the technologist has been provided with emphasis on the use of gloves when handling unsealed radioactive material in the form of radiopharmaceuticals.

B. Regulation 10 CFR 35.50(b)(1) requires in part, that a licensee test each dose calibrator for constancy at the beginning of each day of use.

The violation occurred due to oversight by nuclear medicine technologist in an emergency situation over the weekend. Corrective steps have been taken to ensure that constancy of the dose calibrator is checked prior to its use for the assay of radiopharmaceutical doses by retraining all the technologists in this area. In a new set-up, the technologists are required to sign a posted check-list on the wall in the Hot Lab after completing the constancy check.

C. Regulation 10 CFR 35.60(b) requires that a licensee conspicuously label each syringe or syringe shield which contains a syringe containing a radiopharmaceutical to identify its contents. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed or the patient's name.

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Corrective steps have been taken by obtaining the proper color-coded labels and putting them on syringes or syringe shields which contains a syringe containing a radiopharmaceutical to identify its contents and the name of the patient.

D. Regulation 10 CFR 35.53(c) requires that records of radiopharmaceutical dose assays performed in accordance with 10 CFR 35.53(a) include both the prescribed dose and the activity of the dosage at the time of the measurement.

The form listing radiopharmaceutical prescribed dose was extracted from the Nuclear Medicine Procedure Manual and posted in the Hot Lab for quick reference. Also, the revised form of radiopharmaceutical record now contains columns for both prescribed and assay dose.

E. Regulation 10 CFR 35.92(a)(2) requires licensed radioactive materials disposed of in accordance with 10 CFR 35.92(a) be monitored at the container surface to determine that its radioactivity cannot be distinguished from background levels.

Containers of decayed radioactive material have always been surveyed prior to disposal in regular trash. Short-livedradionuclide waste generated in nuclear medicine is decayed for several months before disposal. Corrective steps have been taken to keep records of each disposal as per regulation 10 CFR 35.92(b).

We will adhere to the applicable NRC regulations and the conditions of our license so that further violations will not occur.

Sincerely,

LARRY E. DETERS
Director

Enclosure:
NRC Letter dated November 7, 1990 (w/encl)

cc:
Nuclear Regulatory Commission
ATTN: Regional Administration, Region II
101 Marietta Street, N.W.
Atlanta, Georgia 30323

VA Central Office
ATTN: Dr. M. D. Grossman
Director, Nuclear Medicine Service (115)
810 Vermont Ave., N.W., Rm. 927-C
Washington, DC 20420

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

NOV 07 1990

Docket No. 030-03250
License No. 41-00104-04

Veterans Affairs Medical Center
ATTN: Mr. Larry E. Deters, Director
1310 24th Avenue, South
Nashville, TN 37203

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 41-00104-04/90-01)

This refers to the inspection conducted by Mr. J. Pelchat of this office on September 19, 1990. The inspection included a review of activities authorized at your facility. At the conclusion of the inspection, the findings were discussed with you.

The inspection was an examination of activities conducted under your license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. It included selective examinations of procedures and representative records, interviews with personnel, and direct observations by the inspector.

The inspection findings indicate that certain activities appeared to violate NRC requirements. The violations, references to pertinent requirements, and elements to be included in your response are described in the enclosed Notice of Violation.

In accordance with 10 CFR 2.790(a), a copy of this letter and its enclosure 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.

Should you have any questions concerning this letter, please contact us.

Sincerely,

William E. Cline, Chief
Nuclear Materials Safety and
Safeguards Branch
Division of Radiation Safety
and Safeguards

Enclosure: (See page 2)

NOV 0 7 1990

Enclosure:
Notice of Violation

cc w/encl:
State of Tennessee

V. A. Central Office
ATTN: Dr. [illegible] D. Grossman, Director
Nuclear Medicine SVS (115)
810 Vermont Ave., NW, Rm. 927-C
Washington, DC 20420

ENCLOSURE

NOTICE OF VIOLATION

Veterans Affairs Medical Center
Nashville, Tennessee

Docket No. 030-03250
License No. 41-00104-04

During an NRC inspection conducted on September 19, 1990, 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 (1990), the violations are listed below:

A. License Condition No. 23 requires that licensed radioactive materials be possessed and used in accordance with the statements, representations, and procedures contained in the radioactive materials license application dated January 11, 1985, and in the documents submitted in support of that application.

Item 15 of the application dated January 11, 1985, states that rules for the safe use of radioactive materials are established in Chapter 4 of the Radiation Safety Manual. Section 4.B.1, page 4-4, of the Radiation Safety Manual states that protective gloves should be worn when radioactive contamination is possible,

Contrary to the above, on September 19, 1985, a nuclear medicine technologist was observed not wearing gloves while handling unsealed radioactive material in the form of radiopharmaceuticals.

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

B. 10 CFR 35.50(b)(1) requires, in part, that a licensee test each dose calibrator for constancy at the beginning of each day of use.

Contrary to the above, on April 9, April 20 and September 9, 1990, the constancy of the dose calibrator was not checked prior to its use for the assay of radiopharmaceutical doses administered to patients.

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

C. 10 CFR 35.60(b) requires that a licensee conspicuously label each syringe or syringe shield which contains a syringe containing a radiopharmaceutical to identify its contents. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

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Contrary to the above, as of September 19, 1990, syringes or syringe shields containing a syringe containing radiopharmaceuticals were not labeled with the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

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

D. 10 CFR 35.53(c) requires, in part, that records of radiopharmaceutical dose assays performed in accordance with 10 CFR 35.53(a) include both the prescribed dose and the activity of the dosage at the time of measurement.

Contrary to the above, as of September 19, 1990, radiopharmaceutical dose assay records did not include both the prescribed dose and the activity of the dosage at the time of measurement.

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

E. 10 CFR 35.92(a)(2) requires that licensed radioactive materials disposed of in accordance with 10 CFR 35.92(a) (Decay-in-Storage) be monitored at the container surface to determine that its radioactivity can not be distinguished from background levels. 10 CFR 35.92(b) further requires that licensees maintain records of radioactive materials disposed of in accordance with 10 CFR 35.92(a).

Contrary to the above, as of September 19, 1990, no surveys were performed of containers containing decayed radioactive materials prior to disposal. Also, contrary to the above, as of September 19, 1990, no records of radioactive materials disposed of in accordance with 10 CFR 35.92(a) were maintained.

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

Pursuant to the provisions of 10 CFR 2.201, Veterans Affairs Medical Center 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 II, 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 reason for the violation, or, if contested, the basis for disputing the violation, (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, an order may be issued to show cause 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.

FOR THE NUCLEAR REGULATORY COMMISSION

William E. Cline, Chief
Nuclear Materials Safety and
Safeguards Branch
Division of Radiation Safety
and Safeguards

Dated at Atlanta, Georgia
this 7th day of November 1990