ELIZABETH GENERAL
EGMC
MEDICAL CENTER

Mailing Address:
925 East Jersey Street
Elizabeth, New Jersey 07201
(201) 289-8600

December 10, 1990

United States Nuclear Regulatory Commission
Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety and Safeguards
Region I
475 Allendale Road
King of Prussia, PA 19406

RE: Routine Inspection No. 030-02437/90-001
Docket No. 030-02437
License No. 29-01600-02

Dear Mr. Shanbaky,

Pursuant to the provisions of 10 CFR 2.201, Elizabeth General Medical Center - West is hereby submitting to your office a written statement in response to your Notice of Violation document dated November 28, 1990.

A. **Syringe Shield Labeling:**

Corrective steps taken:
Following the inspection on October 30, 1990, the Nuclear Medicine Technologists were inserviced concerning radiopharmaceutical record-keeping requirements, including the requirements of labeling syringes as stated in 10 CFR 35.60. The NMT's have incorporated the use of blue and white labels. After preparing a dosage, the abbreviated name of the radiopharmaceutical is written on the label, and the label is attached to the syringe.

Corrective steps to prevent further violations:
The consultant health physicist will on a weekly basis observe the technologists preparing radiopharmaceutical dosages. His observations will assist in compliance with NRC regulations.

Date of full compliance:
November 27, 1990.

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B. Radiation Safety / Pregnancy Policy & Procedures:

Corrective steps taken:
An inservice was presented to the Nuclear Medicine Staff on November 5, 1990 reviewing the departments policy on screening patients for possible pregnancy. The NMT's were also instructed to notify the Radiation Safety Officer (RSO) and health physicist immediately in case a pregnant patient was administered a radiopharmaceutical.

Corrective steps to prevent further violations:
If a pregnant patient has been administered a radiopharmaceutical, the physicist will prepare an estimated fetal dose report. The report will be co-signed by the RSO and the circumstances of the incident will be investigated and discussed at the next Radiation Safety Committee Meeting as required by 10 CFR 35.21. The consultant health physicist will on a monthly basis randomly review patient requisitions to see if the pregnancy question was filled out by the NMT.

Date of full compliance:
December 10, 1990.

C. Molybdenum-99 Breakthrough Correction Factor:

Corrective steps taken:
An inservice was presented to the Nuclear Medicine Staff on November 26, 1990 reviewing radiopharmaceutical record-keeping requirements including the correct method to determine the total molybdenum-99 concentration in each eluate or extract prior to administering that elution to patients. The NMT's were instructed to use the manufacturers correction factor when performing their determination.

Corrective steps to prevent further violations:
A sign has been posted above the dose calibrator to remind the technologists to incorporate the use of the manufacturers correction factor. The consultant health physicist will on a monthly basis review the radiopharmaceutical log-book to make sure the NMT's are complying with 10 CFR 35.204.

Date of full compliance:
November 27, 1990.

D. **Wipe Tests:**

Corrective steps taken:
During the inservice presented on November 26, 1990, the correct procedure for converting net-cpm to dpm was reviewed. Although the protocol was reviewed with the NM Staff, the weekly wipe tests will now be performed by our consultant health physicist.

Corrective steps taken to prevent further violations:
Weekly wipe tests will now be performed by the consultant health physicist with results recorded in dpm.

Date of full compliance:
November 27, 1990.

If you have any questions, please feel free to contact my office at
201-558-8054.

Sincerely,

Lorraine Greiner, R.T.
Administrator
Clinical Services

/tjl
cc: Robert Platt
Robert Silbey, MD, RSO

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

NOV 28 1990

Docket No. 030-02437 License No. 29-01600-02

Elizabeth General Medical Center - West
ATTN; Lorraine Greiner, R.T.
Administrator
Radiologic/Respiratory Therapy Services
925 East Jersey Street
Elizabeth, New Jersey 07201

Gentlemen:

Subject: Routine Inspection No. 030-02437/90-001

On October 23, 1990, Judith A. Joustra and Penny Nessen of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. In addition, our inspection examined the activities covered in your correspondence dated June 26, 1987. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed as Appendix A and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

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Elizabeth General Medical Center - West 2

Your cooperation with us is appreciated.

Sincerely,

M. Shanbaky

Mohamed M. Shanbaky Chief
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

Enclosure:
Appendix A, Notice of Violation

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey
Robert Silbey, M.D., Radiation Safety Officer

APPENDIX A

NOTICE OF VIOLATION

Elizabeth General Medical Center - West
Elizabeth, New Jersey 07201

Docket No. 030-02437
License No. 29-01600-02

As a result of the inspection conducted on October 23, 1990, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1990), the following violations were identified:

A. 10 CFR 35.60(b) requires that licensees conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical and that the label show the radiopharmaceutical name or its abbreviation, the clinical procedures to be performed, or the patient's name.

Contrary to the above, on October 23, 1990, a syringe containing a radiopharmaceutical, had not been labelled as required. Specifically, neither the syringe which contained technetium-99m, nor the syringe shield had been labeled as required.

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

B. 10 CFR 35.21(b)(1) requires, in part, that the Radiation Safety Officer investigate deviations from approved radiation safety practice and implement corrective actions as necessary.

Contrary to the above, on March 6, 1990, the Radiation Safety Officer (RSO) neither investigated deviations from approved radiation safety practice nor implemented corrective actions as necessary when a deviation from approved radiation safety practice occurred. Specifically, the RSO did not investigate the administration of 15 millicuries of Tc-99m (MDP) to a pregnant patient. Determination as to whether the patient was pregnant had not been made prior to administering the radiopharmaceutical, contrary to the licensees established policy and procedure "Protecting The Pregnant Or Potentially Pregnant Patient Who Utilizes Radiological Services."

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

C. 10 CFR 35.204 requires that licensees using molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical determine the total molybdenum-99 concentration in each eluate or extract prior to administering that elution to patients.

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Contrary to the above, as of October 23, 1990, the licensee did not determine the total molybdenum-99 concentration in each eluate or extract prior to administering that elution to patients. Specifically, each eluate was not correctly assayed for molybdenum-99 activity in that the manufacturers correction factor had not been applied.

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

D. 10 [illegible] 35.70(f) requires that a licensee conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

Contrary to the above, as of October 23, 1990, the licensee did not conduct surveys so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute. Specifically, surveys intended to meet this requirement were made, but were inadequately evaluated from September 17, 1990 to October 19, 1990, in that the number of disintegrations per minute had not been calculated correctly. The number of counts per minute had been multiplied by the efficiency rather than divided as required.

This is a Severity Level IV. (Supplement IV)

Pursuant to the provisions of 10 CFR 2.201, Elizabeth General Medical Center - West is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.