



October 17, 1985

United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive - Suite 1000
Arlington, TX 76011

Attn: R. E. Hall, Chief
Radiological and Safeguards
Programs Branch

Docket: 30-14734/85-01
License: 25-16773-02

The following is in response to violations noted by Mr. Russell Wise on July 24 and 25, 1985, and your letter dated September 30, 1985.

A.1. VIOLATION:

1. Item 17 of the application, "Area Survey Procedures," incorporates Appendix I of Regulatory Guide 10.8, Revision 1, October 1980 which requires, in part, that surveys of the elution, preparation, and injection areas be performed daily and that a series of wipe tests to measure contamination levels in laboratory areas be performed weekly.

Contrary to this requirement, daily surveys of the elution, preparation, and injection areas had not been performed during the period July 9, 1984, to May 15, 1985, and weekly wipe tests to measure contamination levels had not been performed during the period April 1979 to July 1985.

EXPLANATION:

This violation appears to have been committed as a result of misunderstanding of license conditions. After discussion with Mr. Wise, license conditions were clarified and requirements referable to this violation are now more clearly understood.

CORRECTION:

- A. Daily surveys, with appropriate low-level survey meter, will be performed in all elution, preparation and injection areas.
- B. Areas of possible contamination within the laboratory area will be wipe tested weekly.
- C. Log of Survey/Wipe Test results will be maintained. Log will be reviewed at quarterly Radiation Safety Committee meetings.

COMPLIANCE:

The above procedures were implemented August 14, 1985.

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A.2. VIOLATION:

2. Item 10 of the application, "Procedures Followed for Dose Calibrator," incorporates Appendix D, Section 2 of Regulatory Guide 10.8, Revision 1, October 1980 which requires, in part, that when in use the constancy tests be performed daily on the dose calibrator and that linearity tests be performed quarterly.

Contrary to this requirement, daily constancy tests were not performed during the period June 3, 1983, to June 13, 1983, when the dose calibrator was used to assay patient doses.

A. CONSTANCY CHECKS

EXPLANATION:

This violation was traced to the fact that a nuclear medicine technologist was not on duty during the period the violation was committed. Nuclear medicine service was provided by radiologic technologists whom, it is now apparent, were unfamiliar with established required procedures.

CORRECTION:

Review of training opportunities was made by the department medical director, technical director, and the staff nuclear medicine technologist. Training procedures were altered and expanded as follows:

All radiologic technologists designated as backup for nuclear medicine procedures will participate in scheduled, recurring rotation through the Nuclear Medicine Service under supervision of a nuclear medicine technologist. Recordkeeping, quality assurance procedures, laboratory procedures, patient imaging procedures, and radiation safety procedures will be reviewed and technologists' educational experience will be recorded. Progress will be reviewed at quarterly Radiation Safety Committee meetings.

COMPLIANCE:

We anticipate full implementation by November 1, 1985.

B. QUARTERLY LINEARITY TESTING

VIOLATION:

Quarterly radioisotope dose calibrator linearity tests were not performed during the third and fourth quarters of 1984.

EXPLANATION:

Linearity tests were performed during the period noted in violation. We were, however, unable to produce documentation to verify test performance. It is our supposition that the documents have been inadvertently destroyed or lost.

CORRECTION:

New recordkeeping and filing procedures have been instituted to reduce the possibility of documents being misplaced. Results of linearity testing will be discussed at quarterly Radiation Safety Committee meetings to provide backup documentation of test performance.

COMPLIANCE:

The above procedure was implemented August 15, 1985.

B. VIOLATION:

The storage room where spent generators are held for decay is located within the Radiology Department, which is accessible to other than Radiology Department personnel during non-regular working hours. This storage room could not be secured to prevent unauthorized removal of radioactive material.

EXPLANATION:

Lack of familiarity with 10 CFR 20.207 (A) led to storage of spent generators being stored in an unsecured area.

CORRECTION:

A lock has been installed on the door to the storage area, keyed to Radiology Department locks only. The lock operates so as to assure the door is secured passively upon closing and can only be opened with the key.

COMPLIANCE:

This device was installed August 21, 1985.

C. VIOLATION:

The storage room in which quantities of licensed materials were stored was not posted with warning signs on July 24, 1985.

EXPLANATION:

Oversight caused the storage area to be maintained without a proper warning sign.

CORRECTION/COMPLIANCE:

"CAUTION
RADIOACTIVE MATERIAL"
sign affixed to the door of the storage area on September 4, 1985.

Sincerely,



Lawrence L. White, Jr.
Administrator