CROZER-CHESTER MEDICAL CENTER

UPLAND, CHESTER, PENNSYLVANIA 19013 - (215) 447-2000

DIVISION OF RADIATION ONCOLOGY
AND NUCLEAR MEDICINE
GEORGE E. McCARTHY, M.D., Director
WARREN SEWALL, M.D.
HOWARD P. ROTHENBERG, M.D.

April 23, 1981

United States
Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406

Re: Docket Nos. 30-03159
70-02426

Gentlemen:

We are responding, as required, to your communication of April 10, 1981 in which you address our activities which were not in full compliance with NRC requirements.

Sincerely,

Howard P. Rothenberg, M.D.

HPR:mlm

NRC COMMENT

A. Condition 18 of your license requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in your application dated April 30, 1979.

1. Item 17 of this application requires that you survey areas used for the elution of Mo-99/Tc-99m generators, for the preparation of radiopharmaceuticals from reagent kits, and for preparation of individual patient doses, and patient injection areas, for contamination after each procedure and/or at the end of each working day.

CCMC RESPONSE

A.1. The following additional areas have been included in our daily surveys for contamination and will be surveyed at the end of each working day and after any procedure where contamination is thought likely. These surveys are documented when done. The areas alluded to are:

a. Hot lab containing generators and radioisotope storage areas.

b. Area around shielded radiopharmaceutical preparation counter.

c. Patient injection area adjacent to nuclear medicine laboratory.

d. Passage between hot lab and nuclear medicine laboratory.

e. Patient waiting area.

f. Patient lavatory.

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NRC COMMENT

A. 2. Item 10 of this application requires that linearity checks of your dose calibrator be performed on a quarterly basis and that the accuracy of this instrument be determined at least annually.

Contrary to this requirement, as of the day of the inspection, March 3, 1981, you last performed a linearity check on the dose calibrator on September 15, 1980, a period exceeding three months, and failed to perform the accuracy determination during 1980, a period of more than one year.

CCMC RESPONSE

A. 2. Linearity of the Capintec CRC-6A dose calibrator was examined and found adequate. Measurements were made on a single elusion of 644 mCi of 99m Technetium Pertechnetate with frequent assays over a three day period from 3/24 to 3/27 with a final assay of 84 uCi. All measurements were found to be within 5% of the predicted value. This procedure will be repeated at quarterly intervals.

Three (3) type E vial standard sources used to check dose calibrator accuracy were themselves checked for accuracy on March 3, 1981. Each vial was measured in the dose calibrator. The measured activity fell within acceptable limits as defined by original calibration accuracy of these standards. The measured activity agreed with the activity predicted from decay calculations based on the original calibrations. This procedure will be repeated at least annually. A decay table for each of the three calibration sources was made so that more frequent accuracy checks of the dose calibrator can be made and those measurements compared with predicted values and logged.

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NRC COMMENT

B. 10 CFR 20.201(b) requires that you make such surveys as may be necessary for you to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to this requirement, you failed to make adequate surveys as were necessary to assure compliance with 10 CFR 20.301, a regulation that describes authorized means of disposing of licensed material contained in waste. Specifically, on the day of the inspection, March 3, 1981, you failed to survey adequately for licensed material in trash cans prior to disposing of the material to the normal trash.

CCMC RESPONSE

B. Instructions to personnel regarding licensed and normal waste disposal have been emphasized to avoid disposal of any radioactive material into unauthorized trash.

All trashcans used by Nuclear Medicine personnel are surveyed for contamination at the end of the day and/or prior to removal to the normal trash.

Housekeeping Department has been given general instructions that trash cannot be removed from the lab before 5:30 PM unless authorized by a Nuclear Medicine Technician.

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NRC COMMENT

C. 10 CFR 35.14(3) requires that sealed calibration or reference sources possessed pursuant to 10 CFR 35.14(d) be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to this requirement, as of the day of the inspection, March 3, 1981, you have failed to leak test your 200 microcurie sealed cesium-137 reference source within the last six months.

CCMC RESPONSE

C. On March 3, 1981 all sealed calibration and reference sources were wipe tested for possible leakage and all showed removed activity well within permissable limits. This procedure will be repeated at six month intervals and the results documented.

NRC COMMENT

D. 10 CFR 20.401(b) requires that you maintain records showing the results of monitoring required by 10 CFR 20.205(b) and (c), Procedures for picking up, receiving, and opening packages."

Contrary to this requirement, as of the day of the inspection, March 3, 1981, you failed to maintain adequate records of the monitoring you performed on incoming packages containing licensed material.

CCMC RESPONSE

D. All in-coming packages to the Nuclear Medicine Department are monitored for possible leakage. Any unusual reading indicating leakage or contamination was recorded at the time of the monitoring. As of March 3, 1981 all such surveys, regardless of the presence of contamination, are recorded at the time of such survey.