CLARA MAASS MEDICAL CENTER

AN AFFILIATE OF RUTGERSCARE

Dec. 13, 1990

Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406

Re: Docket Nos. 030-02467
070-01404

Subject: Routine Inspection
No. 90-001

License Nos. 29-03163-03
SNM-1371

Dear Mr. Shanbaky:

This letter is in response to your letter dated November 28, 1990 concerning our routine safety inspection performed on October 24, 1990 by Judith A Joustra and Penny Nessen as representatives of your office. We appreciate their professionalism and courtesy and found their suggestions very helpful for performing our licence requirements efficiently.

As you indicated in your letter there was some concern that our Radiation Safety Officer (RSO) was not able to exercise his supervisory and program oversight responsibilities for our entire program. We have discussed this at length with him and with the administration of Clara Maass Medical Center. We have determined that it is necessary to hire an additional person highly experienced in Nuclear Medicine procedures to assist in the oversight responsibilities of the Radiation Safety Program in the department. We have placed in the budget funds necessary to hire such a person as a consultant to the Nuclear Medicine Dept who will be available regularly on a bimonthly basis to check all of the safety procedures of the department, and to perform checks of calibrations of all instruments during these visits. The person will also be expected to be available for consultation when any unusual event occurs. That person will report to the RSO who will remain in overall responsibility to see that all of the department activities are in compliance.

In regard to the specific violations cited in your letter under Appendix A, Notice of Violation, the following responses are submitted:

ONE FRANKLIN AVENUE • BELLEVILLE, NEW JERSEY • 07109 • (201) 450-2710 • FAX • 201 450 0184

Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Section A
United States Regulatory Commission

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A. We will continue to monitor the thyroid uptake of all persons involved in the administration of therapeutic doses of radioactive iodine and will maintain a permanent record of these results persuant to the 20.108.

B. 1. Due to a misunderstanding in our previous license we were under the impression that the Radiation Safety Committee only needed to meet biannually. Previous NRC inspectors reviewed the minutes of our meetings and have never cited a violation. The Radiation Safety Committee is now scheduling quarterly meetings and will also be meeting on any occasion where the need arises.

2. a. New reference standards have been ordered for the radionuclides of CS-137, CO-57 and BA-133 of available activity levels. These will be used for the accuracy check required annually and employed for constancy studies as well. These sources have been available but were not of proper size for use in the dose calibrator, or were of low activity.

2. b. The dose calibrator has always been checked on a daily basis for constancy and the results recorded. No indication of a plus or minus 5% variation had been recorded. The results were only approximated by the technologists. At present, this calculation is being made and recorded. When our new CO-57 arrives, a normagram will be developed to rapidly accomplish this calculation daily.

C. All temorary implant removal surveys will be recorded as has been the normal action as per hospital policy. The source inventory log shows that all sources were removed from the patient and returned to storage. These reports will be signed off properly by the physicists and kept in a permanent file.

It is our sincere desire to remain in compliance with all of the safety standards of the Nuclear Regulatory Commission. We trust that these corrective actions will be acceptable to the Commission.

Melvin H. Freundlich, M.D
Director of Nuclear Medicine

Robert S. Curtis, President
Clara Maass Medical Center

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

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Docket Nos. 030-02467
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License Nos. 29-03163-03
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Clara Maass Medical Center
ATTN: Ms. Kerri Johnston
Division Director of Professional Services
1 Franklin Avenue
Belleville, New Jersey 07109

Gentlemen:

Subject: Routine Inspection No. 90-001

On October 24, 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 February 5, 1988. The findings of the inspection were discussed with you and other members of your staff at the conclusion of the inspection.

10 CFR 35.21 requires that licensees appoint a Radiation Safety Officer (RSO) responsible for implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements. Based on our inspection findings and discussions with your staff, it appears that the RSO does not exercise his supervisory and program oversight responsibilities over the entire program. The RSO indicated on several occasions that he is primarily responsible for radiological controls involving radiation therapy.

During the discussion of our finding at the conclusion of the inspection on October 24, 1990 Judith Joustra expressed our concern regarding the responsibilities of the RSO. From these discussions, we understand that your management will address this area of concern. In your response to this letter please identify what actions have been taken or are planned in order to improve your RSO's oversight of your entire radiation safety program.

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.

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
Kenneth Kopecky, Radiation Safety Officer

APPENDIX A

NOTICE OF VIOLATION

Clara Maass Medical Center
Belleville, New Jersey 07109

Docket Nos. 030-02467
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As a result of the inspection conducted on October 24, 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 20.401(c)(1) requires in part that records of individual exposure to radiation and to radioactive material which must be maintained pursuant to the provisions of paragraph (a) of this section and records of bioassays made pursuant to 20.108 shall be preserved until the Commission authorizes disposition.

Contrary to the above, as of October 24, 1990, records of bioassays made pursuant to 20.108 were not preserved until the Commission authorized disposition. Specifically, records of bioassays performed on those who administered therapeutic quantities of liquid iodine-121 to patients were not preserved by the licensee.

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

B. Condition 16 of License No. 29-03163-03 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated December 18, 1984.

1. Item No. 7 of this application requires that the responsibilities, duties and meeting frequency of the Radiation Safety Committee (Medical Isotope Committee) be as described in Appendix B of Regulatory Guide 10.8 (Rev. 1).

Appendix B of Regulatory Guide 10.8 requires the Radiation Safety Committee meet as often as necessary to conduct its business but not less than once in each calendar quarter.

Contrary to the above, as of October 24, 1990, the Radiation Safety Committee met to conduct business less than once in each calendar quarter. Specifically, the Radiation Safety Committee only met two times per year.

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

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2. Item No. 10 of this application requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8. (Rev. 1).

   a. Item A of Appendix D requires that the dose calibrator accuracy be tested at installation and annually thereafter.

      Contrary to the above, as of October 24, 1990, the dose calibrator accuracy had not been tested annually.

   b. Item C of Appendix D requires that the dose calibrator daily constancy check include an indication of the predicted activity of each source used based on decay and a determination of variation greater than ±5% from the predicted activity.

      Contrary to the above, as of October 24, 1990, the dose calibrator daily constancy check did not include a determination of variations greater than ±5% from the predicted activity. Specifically, this determination had not been made since November 1988.

   These are Severity Level IV violations. (Supplement VI)

C. 10 CFR 35.404 requires that immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed and to retain a record of patient surveys for three years.

   Contrary to the above, as of October 24, 1990, the licensee did perform the required patient surveys but did not retain a record of the patient surveys for three years. Specifically, records for six temporary implants, which were performed between March 1, 1990 and August 31, 1990, were not retained.

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

Pursuant to the provisions of 10 CFR 2.201, Clara Maass Medical Center 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.