U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Combined Report Nos. 030-01847/94-001 & 030-00234/94-001

EA No. 94-099

License Nos. 20-02452-01 Priority 3 Category 3
20-02452-03 Priority 1 Category G3

Docket Nos. 030-01847
030-00234

Licensee: Medical Center of Central Massachusetts - Memorial
119 Belmont Street
Worcester, Massachusetts 01605-2982

Facility Name: Medical Center of Central Massachusetts - Memorial

Inspection at: 119 Belmont Street
Worcester, MA 01605-2982

Inspection Date: May 23 - 24, 1994

Inspector: Sattar Lodhi, Ph.D., Health Physicist — 6-10-94 Date

Approved by: Jenny M. Johansen, Chief
Medical Inspection Section — 6-10-94 Date

Inspection Summary: Routine unannounced inspection conducted on May 23 and 24, 1994 (Combined Report Nos. 030-01847/94-001 & 030-00234/94-001).

Areas Inspected: Review of activities authorized by the NRC licenses including: radiation safety program management and implementation; nuclear medicine and radiation therapy.

Results: Twelve apparent violations were identified: (1) Failure to establish a quorum at a Radiation Safety Committee meeting (Section 3); (2) failure to include the signature of the Radiation Safety Officer in the records of leak test and inventory of the sealed sources (Section 3); (3) failure to supply and require the use of individual monitoring devices by personnel working in restricted areas (Section 3); (4) failure to include in the quality management program written policy and procedures to meet the objective that prior to administration, a written directive is prepared for any brachytherapy radiation dose or any administration of therapeutic radiopharmaceuticals other than sodium iodide I-131 (Section 4); (5) failure to instruct individuals working in restricted areas in the applicable provisions of the Commission's regulations (Section 5); (6) failure to include the description of the size and appearance of brachytherapy sources in radiation safety instructions to nursing personnel (Section 5); (7) failure to control and maintain constant surveillance of licensed material in an unrestricted area and not in storage (Section 6); (8) failure to test the dose calibrator for linearity over the entire range of its use (Section 6); (9) failure to ensure that radiation safety activities are being performed in accordance with approved procedures (Section 6); (10) failure to post the clearance time in rooms where xenon-133 is administered (Section 6); (11) failure to limit the use of a teletherapy unit to medical purposes (Section 7); (12) failure to determine timer linearity over the range of use (Section 7).

DETAILS

1. Persons Contacted

*Laurence E. Kelly, Vice President/Professional Services
*James J. Hoogasian, Administrative Director, Cancer Services & Authorized User
*James Merrill, Manager, Radiation Oncology
*James W. Adams, Manager, Nuclear Medicine
Peter B. Schneider, M.D., Co-Director of Nuclear Medicine & Authorized User (Nuclear Medicine)
Norio Higano, M.D., Radiation Safety Officer & Authorized User (Nuclear Medicine)
Won K. Tak, M.D., Authorized User (Radiation Oncology)
Mabini M. Castro, Teletherapy Physicist
George Boateng, Nuclear Medicine Technologist
Margaret Emmons, Nuclear Medicine Technologist
Diane Ryan, Nuclear Medicine Technologist
Patricia Roy, Medical Secretary
Mary Sliwowski, Assistant Nurse Manager
Patricia Plant, House Worker

2. Organization and Scope of the Licensee Program

The Medical Center of Central Massachusetts possesses two byproduct material licenses. License No. 20-02452-01 authorizes the use of licensed materials for medical diagnostic studies, radiopharmaceutical therapy, brachytherapy, the use of certain byproduct materials in research, and cesium-137 for calibration and checking of instruments. License No. 20-02452-03 authorizes the use of cobalt-60 sealed sources in an AECL Theratron 780C teletherapy unit which is to be used as described in 10 CFR 35.600 and depleted uranium as shielding in the unit. The licensed activities are conducted in the departments of Nuclear Medicine, Radiation Oncology and Research. Currently, the research activities do not involve the use of licensed materials.

3. Program Management & Implementation

The Licensee has established a Radiation Safety Committee (RSC) and has appointed a Radiation Safety Officer (RSO) to oversee the use of byproduct material. The

Managers of the Nuclear Medicine and the Radiation Oncology departments provide assistance to the RSO in the discharge of his responsibilities related to their respective departments. The membership of RSC meets the regulatory requirements and its meetings are held quarterly. The designated representative of the management in the RSC is the Vice President for Professional Services and the RSO is also the Chairman of the Committee. The inspector noted that the designated representative of management was present in only one out of the eight RSC meetings held during 1992 and 1993. The manager of Nuclear Medicine stated that he represented the management at the RSC meetings whenever the designated representative of the management could not attend the meeting. However, at the conclusion of the inspection, the designated representative of the management stated that another individual (Director of Research) and not the Manager of Nuclear Medicine represented the management at the RSC meetings. The inspector noted that the Director of Research is also an authorized user and therefore, did not meet the criteria established in 10 CFR 35.22(a)(1) for the representative of the management. The inspector also noted that neither the designated representative of the management nor his designated alternate representative attended the RSC meeting that was held on March 12, 1992. 10 CFR 35.22(a)(3) requires, in part, that to establish a quorum and to conduct business, at least one-half of the Committee's membership must be present including the RSO and the management's representative.

Failure of the representative of the management to attend the RSC meeting is an apparent violation of 10 CFR 35.22(a)(3).

The inspector noted that the records of quarterly inventory of sealed sources conducted on January 3, 1994 and March 23, 1994 were not signed by the RSO. The inspector also noted that the records of the leak tests of the sealed sources performed on March 23, 1994 did not include the signature of the RSO. 10 CFR 35.50(d) and (g) require, in part, that the leak test records and the quarterly inventory records of the sealed sources also contain the signature of the RSO.

Failures to include the signature of the RSO in the leak test and inventory records of the sealed sources are apparent violations of 10 CFR 35.59(d) and (g) respectively.

The inspector noted that the Licensee supplied and required the use of personnel monitoring equipment in accordance with the requirements of 10 CFR 20.1502. The film badges are processed every month and the records are maintained showing the radiation exposures of all individuals for whom personnel monitoring is required by 10 CFR 20.1502. However, the inspector noted that the Licensee allowed an individual (a temporary nuclear medicine technologist) to work in the nuclear medicine department from April 4, 1994 to April 22, 1994, without providing this individual a film badge. The individual used a film badge supplied by his agency.

The inspector stated that because this individual may have used the same film badge at other facilities that his agency provided services to, the Licensee could not determine the exposure of this individual that may have occurred at its facility. 10 CFR 20.1502(a) requires, in part, that each licensee supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(b).

Failure to supply and require the use of individual monitoring devices by the temporary nuclear medicine technologist is an apparent violation of 10 CFR 1502(a).

The inspector also noted the presence of a minor in the hall way in front of the nuclear medicine hot lab. The inspector determined that this minor routinely stays in the Nuclear Medicine department during the late afternoon hours about three or four days a week. The Manager of Nuclear Medicine stated that he did not consider this to be a concern because the hall way was an unrestricted area. The Vice President however, agreed with the inspector that it was not a good practice to allow minors to frequent the areas of the Nuclear Medicine department and that corrective action will be initiated.

4. Quality Management Program & Internal Audits

The Licensee has established a written quality management program (QMP) for the administrations of radiopharmaceutical therapy and radiation therapy. The Managers of Nuclear Medicine and Radiation Oncology departments conduct periodic audits of the activities in their respective departments to verify that these activities conform to the requirements of the QMP. The reports of these audits are submitted to the Licensee's Quality Assurance Committee (QAC) by the RSO. The latest audit of the activities in the Nuclear Medicine department from March 1993 through March 1994 was completed, and a report dated May 11, 1994, was submitted to the QAC stating that the objectives of the QMP were met. The inspector noted that the report of the annual review of the activities in the Radiation Oncology department did not document verification of compliance with the Licensee's QMP. The Manager of Radiation Oncology, however, stated that the review did include the verification of compliance with the QMP.

The inspector reviewed the written directives for radiopharmaceutical therapy and radiation therapy administrations. In addition to iodine-131 therapy dosages, the Licensee also administers radiopharmaceutical therapy dosages of phosphorus-32 and strontium-89 to patients. These dosages are administered by the authorized users. The inspector noted that on April 21, 1994 and on April 25, 1994, the Licensee

administered 4.0 and 3.8 millicurie dosages respectively, of strontium-89, and on May 9, 1994, a 6 millicurie dosage of phosphorus-32 was administered and the written directives for these administrations did not include the route of administrations. Similarly, radiation therapy dosages are administered by the use of the teletherapy unit and also by implant procedures. The inspector reviewed four written directives for the administration of radiation doses by the use of teletherapy unit and noted that these directives were not dated by the authorized user but did include the date of simulation of treatment. The authorized user stated that the simulation date is the same as the date on which the directive is written. However, he stated that in future, the authorized user will include the date when he signs the written directive.

The inspector noted that the written directives for brachytherapy procedures did not include all of the required information. For example, on March 25, 1994, the authorized user wrote a directive to administer a radiation dose of 4000 centigray to a patient. The directive did not include the isotope and the number of sources. Similarly, the authorized user wrote a directive for a brachytherapy procedure to be performed on January 10, 1994, and the directive did not include the date, the source strengths and the site of implant. 10 CFR 35.32(a) requires, in part, that the QMP include policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any brachytherapy radiation dose or any therapeutic administration of a radiopharmaceutical.

Failure to include in the QMP, policies and procedures to meet the objective that, prior to administration of a brachytherapy dose or therapeutic radiopharmaceutical dosage, a written directive is prepared is an apparent violation of 10 CFR 35.32(a).

5. Training

The Licensee's training program provides an initial training to newly employed personnel in the radiation safety procedures appropriate to the employee's duties. Annual refresher training is also provided to workers. The Managers of the Nuclear Medicine and Radiation Oncology are responsible for providing the training. Nursing personnel responsible for providing care to patients undergoing radiopharmaceutical therapy or brachytherapy are provided training via a video training film. The Nuclear Medicine Technologists (NMTs) are also required to complete a minimum of 4 credit hours of course work appropriate to their duties.

The Licensee administers radioactive xenon-133 gas for lung ventilation in the Nuclear Medicine department. The inspector determined that at least two NMTs were not instructed in the appropriate emergency procedures in case of xenon-133 release. Neither of these two NMTs knew what the clearance time was, or where to look for

it. 10 CFR 19.12 requires, in part, that all individuals working in any portion of a restricted area be instructed in the precautions or procedures to minimize exposure to radioactive material or radiation.

Failure to instruct nuclear medicine technologists in emergency procedures related to xenon-133 spills is an apparent violation of 10 CFR 19.12.

The inspector interviewed the Licensee's nursing personnel who provided care to patients who had been undergoing brachytherapy treatment and determined that the nursing personnel were not provided training in the size and appearance of brachytherapy sources. 10 CFR 35.410(a) requires, in part, that the radiation safety instruction to personnel caring for the patient undergoing implant therapy also include the description of the size and appearance of the brachytherapy sources.

Failure to instruct the personnel caring for the brachytherapy patients in the size and appearance of the brachytherapy sources is an apparent violation of 10 CFR 35.410(a).

6. Nuclear Medicine

The Licensee has an active diagnostic and therapeutic nuclear medicine program. There are seven NMTs and three authorized users. There are three cameras each located in a separate room. The department operates between 7:30 a.m. and 4:45 p.m. on week days. Between 10 and 15 diagnostic procedures are performed each day using radiopharmaceuticals containing technetium-99m, thallium-201, xenon-133, iodine-123, iodine-131, gallium-67, indium-111 or chromium-51. The Licensee does not use generators and the radiopharmaceuticals are obtained from commercial nuclear pharmacies. Approximately 20 therapeutic dosages of iodine-131 (in liquid form) are administered annually, most of which are under 30 millicuries. Iodine-131 dosages that do not require hospitalization are administered in the hot lab. Occasionally therapeutic dosages of phosphorus-32 and strontium-89 are also administered. All therapeutic radiopharmaceutical dosages are administered by one of the authorized users in the injection room or in the hot lab.

The radiopharmaceuticals are stored and prepared for administration in the nuclear medicine hot lab. The hot lab door opens into a hall way which was described by the Manager of Nuclear Medicine to be an unrestricted area.

Upon his arrival at the facility on May 23, 1994, the inspector noted that the doors to the Nuclear Medicine hot lab was wide open and there was no one controlling the access to the hot lab where licensed material was stored for use. The inspector

announced his presence but no one responded. The inspector was able to gain entry to the hot lab unchallenged and observed that a few vials containing radioactive materials were in the hot lab. The inspector remained in front of the opened door until he saw a secretary in the hall way and requested her to send some one to secure the material stored in the hot lab. She contacted the manager of Nuclear Medicine department who came to the hot lab. The inspector determined that the licensed material stored in the hot lab at the time included a vial containing 900 millicuries (calibrated for May 24, 1994) of technetium-99m, a second vial containing 183 millicuries of technetium-99m (MDP), and a vial containing 6 millicuries of iodine-131 in the liquid form. The Manager of Nuclear Medicine stated that usually there is some one in the hot lab. The Co-Director of Nuclear Medicine stated that entry to this hall way is controlled and there is a sign posted indicating that the entry to the hall way was limited to authorized personnel. The inspector stated that he did not notice that a control was in effect as he was able to enter the hall way and the hot lab unchallenged. On two subsequent occasions on the same day, the inspector again noted that the door to the hot lab was left opened and no one was in the hot lab or in the hall way and requested the manager of Nuclear Medicine to secure the licensed material. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in an unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Failure to keep the licensed material under constant surveillance and immediate control of the licensee is an apparent violation of 10 CFR 20.1802.

Upon his arrival in the Nuclear Medicine department in the morning of the following day (May 24, 1994), the inspector noted that the door to the hot lab was unlocked and no one was in the hot lab or in the hall way. The inspector again requested the Manager of Nuclear Medicine that the security of the licensed material be maintained.

The Licensee uses a dose calibrator to measure the radiopharmaceutical dosages prior to the administration. A review of records of the linearity tests of the dose calibrator indicated that these tests were not performed over the entire range of use between the highest dose measured and 10 microcuries as required by 10 CFR 35.50(b)(3). The linearity tests performed on October 25, 1993, August 3, 1993, May 17, 1993, February 22, 1993, November 23, 1992, August 31, 1992 and June 2, 1992 covered the range from the highest dosage measured to 102.7 microcuries, 133.2 microcuries, 104 microcuries, 80 microcuries, 188.7 microcuries, 119 microcuries, and 161.5 microcuries, respectively. Similarly, the linearity test performed on September 17, 1991 did not include the highest dosage that the Licensee measured. The Licensee used the dose calibrator on October 15, 1991, to measure an iodine-131 dosage of 98 millicuries and the dose calibrator was tested for linearity only between 44.8

millicuries and 5 microcuries. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Failure to test the dose calibrator between the highest dosage that will be administered to a patient and 10 microcuries is an apparent violation of 10 CFR 35.50(b)(3).

The Licensee possesses appropriate radiation survey instruments and uses these instruments to ensure compliance with regulatory requirements. These survey instruments are calibrated annually. The inspector noted that the three survey instruments, namely, a Ludlum Model 5, a Victoreen Model 740F and a Baird Model 420 that are used in the Nuclear Medicine department were calibrated by the Licensee on November 2 and 3, 1993. The Licensee's procedures for calibration of survey instruments are described in its application dated November 12, 1990, and were approved by Condition No. 24 of NRC License No. 20-02452-01. The Licensee is committed to use the Model Procedure for Calibrating Survey Instruments which is described in Appendix B to Regulatory Guide 10.8, Revision 2. This procedure requires, in part, that the source be of sufficient strength to give an exposure rate of about 30 milliroentgen per hour at a distance of 100 centimeter, and that each linear scale of the instrument be calibrated at no less than two points. The inspector noted that the Licensee used three different brachytherapy (cesium-137) sources with activities of 40.2 millicuries, 2.12 millicuries, and 1.08 millicuries. The maximum exposure rate that any one of these sources could provide was 13.2 milliroentgen per hour at a distance of 100 centimeters. The inspector also noted that each of the linear scales of these survey instruments was calibrated only at one point.

10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures.

Failure to follow approved procedures for the calibration of survey instruments is an apparent violation of 10 CFR 35.21(a).

The Licensee has two rooms in the nuclear medicine department where xenon-133 is administered to patients. These rooms are ventilated to the outside but the clearance time was not posted in either of the two rooms. The Manager of Nuclear Medicine was unable to readily locate the calculations or the actual time of clearance. The calculations and a blue print of the rooms with the clearance time were later located by the Co-Director of Nuclear Medicine. 10 CFR 35.205(d) requires, in part, that the calculated clearance be also posted.

Failure to post the clearance time is an apparent violation of 10 CFR 35.205(d).

7. Radiation Oncology

The Licensee uses a linear accelerator (Varian 2100-C) and a Theratron 780C teletherapy unit to administer radiation therapy. In addition, the Licensee also performs brachytherapy procedures. There are two authorized users, one physicist, one dosimetrist and four full time radiation therapy technologists. The licensee administers approximately 40 treatments each day using its linear accelerator. Since May 1, 1994, the teletherapy unit has been used to administer approximately 15 treatments each day. The Manager of Radiation Oncology stated that the teletherapy unit is also used to irradiate blood samples. The last time the unit was used an irradiator was on May 18, 1994. The inspector stated that the Licensee is authorized to use the teletherapy unit for medical purposes and approval from the NRC is required prior to any other use of the teletherapy unit . The Licensee's approved use of its teletherapy unit is described in Condition No. 9 of NRC License No. 20-02452-03. Condition No. 9 states, in part, that the byproduct material listed in Condition No. 6 of the License is for medical use described in 10 CFR 35.600.

Failure to limit use of the teletherapy unit to medical use as described in the NRC license is an apparent violation of Condition No. 9 of NRC License No. 20-02452-03.

The Licensee last performed full calibration of its teletherapy unit on January 26, 1994. The full calibration and the monthly spot checks included the determination of timer linearity over a range of one minute. However, the inspector noted that the range of use included time intervals of more than one minute. For example, on May 23, 1994, a patient was given treatment for 2.1 minutes. 10 CFR 35.632(b)(3) requires, in part, that the annual full calibration include the determination of timer linearity over the range of use.

Failure to determine the timer linearity over the range of use is an apparent violation of 10 CFR 35.632(b)(3).

8. Research

The Director of Research stated that licensed material was not being used in the research lab and therefore this area of licensed activity was not reviewed during the inspection.

9. Radioactive Waste Disposal

The inspector reviewed records of waste disposal and interviewed the Chief Nuclear Medicine Technologist regarding the Licensee's waste disposal program. The Nuclear Medicine Department uses the decay-in-storage method of waste disposal. The inspector determined that the Licensee holds radioactive waste for decay-in-storage at least ten half-lives and that the Licensee performs a survey to assure that the activity of the decayed waste cannot be distinguished from background radiation levels prior to disposal in the normal trash.

No violations were identified.

10. Exit Interview

At the conclusion of the inspection, the inspector met with the Licensee's representatives designated in Section 1 of this report. The inspector summarized the scope and findings of the inspection. The Vice President stated that he would take immediate corrective actions to ensure the security of licensed material and that he would personally verify that the corrective actions are being implemented. During a conversation with Region I staff on June 1, 1994, he confirmed that corrective actions have been implemented to ensure the security of radioactive material.