U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report Nos. 030-02984/94-001
030-00465/94-001

EA No. 94-066

Docket Nos. 030-02984 Priority 1 Category G1
030-00465 1 G3

License Nos. 37-01421-01
37-01421-04

Licensee: Geisinger Medical Center
100 North Academy Avenue
Danville, Pennsylvania 17822

Facility Name: Geisinger Medical Center

Inspection At: 100 North Academy Avenue
Danville, Pennsylvania 17822

Inspection Conducted: March 29-31, 1994

Inspectors: _____ May 4, 1994
Ihor Czerwinskyj, Health Physicist date
Medical Inspection Section

Approved by: _____ May 4, 1994
Jenny M. Johansen, Chief date
Medical Inspection Section

Inspection Summary: Unannounced safety inspection conducted March 29-31, 1994 (Inspection Reports Nos. 030-02984/94-001 and 030-00465/94-001), and a special safety inspection conducted on April 25, 1994.

Areas Inspected: Licensee actions on previous violations; scope; Radiation Safety Committee; nuclear medicine program; radiation therapy program; irradiator; research program; personnel radiation protection; waste disposal; misadministration; and quality management program.

Results: Three apparent violations were identified: 1) Failure to contact the RSO immediately after discovery of an abnormal operation of a teletherapy unit control mechanism (Details, Section 6.3); 2) Failure to notify NRC within 24 hours of a event in which equipment failed to function as designed to prevent radiation exposures (Details, Section 6.3); 3) Failure to perform full calibration following repair of a control component associated with the source exposure assembly (Details, Section 6.3).

DETAILS

1.0 Persons Contacted (During the March 29-31, 1994 Inspection)

* Catherine Anderko, Radiation Safety Officer
* Deborah Watson, Administrative Director of Operations
Laverne Reed, Chief NMT
John Glover, Ph.D., Therapy Physicist
Gerry Spencer, Oncology Manager
Marcus Brown, M.D., Oncologist
Ramzi Kattan, M.D., Oncologist
David Brill, M.D., Chairman of the Radiation Safety Committee
Virginia Kane, Co-60 Therapy Technologist
David Shoemaker, Blood Bank Supervisor
Diane Maturani, RIA Lab Supervisor
Douglas Heim, Health Physicist
Lisa Strawser, NMT

* Present at Exit Conference on March 31, 1994

1.1 Persons Contacted during the April 25, 1994 special inspection

* Catherine Anderko, Radiation Safety Officer
Douglas Heim, Health Physicist
* Deborah Watson, Administrative Director of Operations

* Present at Exit Conference on April 25, 1994

2.0 Licensee Action on Previous Violations

2.1 (Closed) Violation (Inspection 93-001); Disposing of licensed material by incineration without a specific approval by the Commission.

The inspector determined that RIA Lab waste is being stored for decay-in-storage and not incinerated.

2.2 (Closed) Violation (Inspection 93-100) Failure of the Radiation Safety Officer to survey each lab at least twice annually.

The inspector reviewed records of Radiation Safety Officer's surveys and determined that all labs were surveyed at least twice annually.

2.3 (Closed) Violation (Inspection 93-001) Failure to perform geometry dependance calibration, following a repair of dose calibrator.

The inspector reviewed a record of the performance of the geometry dependence calibration dated April 20, 1993.

2.4 (Closed) Violation (Inspection 93-001) Failure to keep records for surveys for removable contamination in disintegrations per minute per 100 square centimeters.

The inspector noted that for all records of surveys for removable contamination performed since the last inspection, the results were expressed in dpm per 100 square centimeters.

3. Scope

The licensee currently possesses two NRC licenses. License No. 37-01421-01 authorizes the use of licensed materials for medical diagnosis, therapy and research and development including medical research in humans in accordance with applicable Food and Drug Administration regulations; a cesium-137 sealed source in an AECL Gammacell 1000 irradiator; and a Nucletron Corporation high dose rate (HDR) remote afterloading brachytherapy unit. License No. 37-01421-04 authorizes the possession and use of a cobalt-60 sealed source in an AECL Theratron 780 teletherapy unit for therapy in humans. License No. 37-01421-01 authorizes the use of the licensed materials in Danville, Wilkes-Barre and Lock haven, Pennsylvania. License No. 37-01421-04 limits the use of the cobalt-60 teletherapy unit to the Danville, Pennsylvania facility.

This inspection was limited to activities at the Danville, Pennsylvania facility.

4. Radiation Safety Committee

The inspector reviewed the minutes of the Radiation Safety and Isotopes Committee. The meetings of the Committee were held once every two months. The inspector determined that the Radiation Safety and Isotopes Committee (RSIC) was composed of appropriate personnel as required. A review of the RSIC's meeting minutes indicated that the matters pertinent to Radiation Safety including ALARA were discussed.

No safety concerns were identified.

5. Nuclear Medicine Program

The inspector toured the nuclear medicine department, interviewed nuclear medicine technologists, reviewed area radiological survey records, dose calibrator quality control tests, and patient dosage records. The Nuclear Medicine Department was staffed with eight technologists. The department performs around 400 procedures per month. They also perform radiopharmaceutical therapy with iodine-131 and strontium-89. Seventeen iodine-131 therapies using 30 millicuries or more for treatment of thyroid carcinoma

were performed in 1993. Nineteen administrations of strontium-89 for bone metastases were performed since August 12, 1993. The Department receives a 2.7 Curie technetium generator each week on Monday mornings.

No safety concerns were identified.

6. Radiation Therapy Program

The Radiation Oncology Department is responsible for the use of cesium-137, iridium-192, and iodine-125 sealed sources for conventional brachytherapy, an iridium-192 sealed source in a high dose rate (HDR) remote afterloading brachytherapy unit, and the cobalt-60 teletherapy unit.

6.1 Conventional Brachytherapy

In 1993, there were twenty-one cesium-137, five iridium-192, and one iodine-125 seed implants. The inspector reviewed licensee's brachytherapy room survey records and noted that the dose rates in the unrestricted areas were 2mR/hr or less.

No safety concerns were identified.

6.2 High Dose Rate Brachytherapy

The licensee possesses a Nucletron Corporation MicroSelectron High Dose Rate remote afterloading brachytherapy unit. In 1993, the unit was used to treat 24 patients. The licensee has adopted the recommendations in NRC Bulletin 93-01 and requires that the authorized user physician and a medical physicist be present for any patient therapy. The hospital has a contract with Nucletron Company to provide initial and annual training, change the source, perform preventive maintenance at each source change, and provide any emergency repairs. The inspector reviewed all pertinent records of training, preventive maintenance, calibration and surveys after each source change.

No safety concerns were identified.

6.3 Cobalt-60 Teletherapy (License No. 37-01421-04)

The licensee uses an AECL Theratron 780 cobalt-60 teletherapy unit to deliver external beam therapy. The cobalt unit is used mainly for treatment of metastatic bone and brain tumors. Currently the licensee treats five patients per day. The last source change was performed by Theratronics in December of 1987. The activity of the source installed was 6,338 curies of cobalt-60. On June 11, 1993, Theratronics conducted the required 5-year inspection.

During a review of the minutes of the May 17, 1993 meeting, of the Radiation Safety and Isotopes Committee, the inspector noted that in late March of 1993, the main timer on the cobalt-60 teletherapy unit failed, so that termination of exposure from the unit did not occur automatically. The inspector requested and received a full report of the incident prepared by the RSO on April 3, 1993. The problem was identified on Wednesday, March 31, 1993, by the radiation therapist, a technologist, who immediately notified a teletherapy physicist and the department manager. The radiology engineer cleaned and oiled the timer, which provided temporary relief from the malfunction. However, the problem recurred. The radiation therapist was instructed by the teletherapy physicist to continue to use the cobalt-60 teletherapy unit by using the back-up timer and physically terminating the exposure time, since the back-up timer was not capable of terminating the exposure automatically. A new timer was ordered, with the installation scheduled for Monday, April 5, 1993. At this time there were twelve patients being treated by the cobalt teletherapy unit. Because the radiation therapist felt this was an unsafe situation, she reported the situation to the RSO on April 2, 1993. The RSO investigated this matter on Friday, April 2, 1993, and ordered the unit be put out of service until the timer could be replaced. The timer was replaced by Theratronics on April 5, 1993. The teletherapy physicist performed a monthly cobalt output spot-check on April 5, 1993, and the unit was returned to service.

10 CFR 35.610(a)(2)(ii) requires that the licensee post instructions at the teletherapy console which must inform the operator of the procedures to be followed if the teletherapy unit or console operates abnormally and the names and telephone numbers of the authorized user and the Radiation Safety Officer to be contacted immediately if the teletherapy unit or console operates abnormally.

Failure to inform the RSO immediately after discovering a major failure of the teletherapy control is an apparent violation of 10 CFR 35.610(a)(2)(ii) and of the Emergency Procedures posted on the bulletin board next to the teletherapy operating console.

10 CFR 30.50(b)(2)(i) requires the licensee to notify the NRC within 24 hours after discovery of an event in which equipment is disabled or fails to function as designed and the equipment is required by regulation or license condition to prevent exposures to radiation exceeding regulatory limits, or to mitigate the consequences of an accident.

Failure of the licensee to notify the NRC within 24 hours following the discovery of an event in which a teletherapy timer failed to function as designed is an apparent violation of 10 CFR 30.50(b)(2)(i).

10 CFR 35.632(a)(2)(iii) requires the licensee to perform full calibration measurements on each teletherapy unit following any repairs of the components associated with the source exposure assembly.

Failure of the licensee to perform full calibration of the teletherapy unit following a replacement of a component associated with the source exposure assembly is an apparent violation of 10 CFR 35.632(a)(iii).

7. Irradiator

The licensee uses a Gammacell 1000 irradiator containing 651 curies of cesium-137 as of September 1982. The irradiator is located in the Blood Bank and is mainly used to inactivate lymphocytes in the blood. The inspector interviewed a user and the supervisor of the unit and reviewed records of use.

No safety concerns were identified.

8. Research Program

Currently there are thirteen labs authorized to use radioactive materials. Each lab is surveyed for removable contamination at least monthly by the authorized user, and quarterly, or semi-annually, by the Radiation Safety Office. The inspector reviewed authorizations for research use of licensed materials, monthly survey records, incident reports and RSO surveys.

No safety concerns were identified.

9. Personnel Radiation Protection

Records of personnel exposures from March 1993 to January 31, 1994 were reviewed. The licensee uses vendor dosimeters which are exchanged monthly. Several doses were in excess of the licensee's "As Low As Reasonably Achievable" (ALARA) levels. The licensee's RSO reviewed and investigated all exposures in excess of ALARA levels.

Bioassays are performed on all personnel who administer therapeutic doses of iodine-131. Bioassays are also performed on researchers who perform iodination with iodine-125. All results of bioassays examined by the inspector indicated no uptakes have occurred. In addition, for iodination procedures, a breathing zone and effluent air samples are performed. The results of all samplings for airborne iodine activity in the breathing zones and effluents during 1993 and 1994 did not exceed 10% of Part 20 limits.

No safety concerns were identified.

10. Waste Disposal

The inspector reviewed the licensee's waste disposal methods and records. The licensee uses decay in storage method of disposal in Nuclear Medicine. In the research laboratories, the waste generated is stored for pick-up by the RSO's staff and consolidated in one of three waste storage areas for eventual transfer to a waste broker.

No safety concerns were identified.

11. Misadministrations

The licensee's RSO stated that no misadministrations had occurred since the last inspection. The inspector reviewed the licensee's Quality Management Program Audits and representative patient records. No misadministrations were identified.

11.1 Iodine-131 MIBG Incident

On April 18, 1994 the licensee notified the NRC Operations Center of a possible misadministration of iodine-131 to a three and one-half year old patient. The inspector conducted a special safety inspection of the licensee facility on April 25, 1994. By reviewing records and interviewing pertinent personnel the inspector determined that no misadministration occurred. A three and one-half year old female patient was supposed to receive, by injection, a 157 uCi dose of iodine-131 MIBG. A proper written directive was prepared for the iodine-131 MIBG, which is an investigational drug, supplied to the licensee under an IND by University of Michigan Phoenix Laboratory. The drug is supplied in 2.2 millicurie vials. The technologist, by mistake, withdrew 515 uCi of the drug and injected the patient. After completing the injection, the technologist realized his mistake. He reported the error assayed, and the licensee determined that 85 uCi remained in the syringe and in the IV tubing. The licensee determined that the patient received SSKI (potassium iodide), one drop three-times a day for one day before injection. In addition, SSKI was administered to the patient three times a day for six days after injection. On April 22, 1994, the patient received a whole-body scan; no activity over background was found in the patient's thyroid. The licensee determined that the largest organ committed exposure for the patient, caused by the Iodine MIBG dose, was 42.73 rads to the adrenal medula. The normal exposure to the adrenal medula from the correct dose would be 15.60 rads.

The referring physician was notified. The physician notified the patient's family. The licensee conducted a complete investigation of the incident and determined that the cause of the incident was a random error by the technologist. The technologist was counselled and a letter of reprimand was entered in his personnel file. In addition, an in-service on Quality Management Program was provided to the whole Nuclear Medicine Staff. In the future two technologist will check the dose of I-131 MIBG before administering the dose to the patient. The inspector reviewed all pertinent calculations and concurred with the licensee's determination of organ dose. The inspector determined that no misadministration occurred, even though the administered dosage of a diagnostic radiopharmaceutical differed from the prescribed dose by more than twenty percent, the total whole body dose to the patient was calculated to be less than 5 rems effective dose equivalent and the effective dose equivalent to any individual organ was calculated to be less than 50 rems.

12. Quality Management Program

The inspector verified that the licensee had submitted a quality management program (QMP) on September 13, 1991 and a modified QMP on September 30, 1993. The licensee performed audits of their QMP as required. Several minor recording discrepancies were identified by the licensee, and those were brought to the attention of respective authorized users for correction. All staff were trained on the modified QMP in August 1993.

No safety concerns were identified.

13. Exit Interview

The inspector met with the licensee's representatives designated in Section 1 of this report at the conclusion of the inspection. The inspector summarized the scope and findings of the inspection.