U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-10838/92001(DRSS)

License No. 34-16241-01 Category G Priority 2

Licensee: Lawrence County Medical Center
2228 South 9th Street
Ironton, OH 45638

Inspection Conducted: October 1, 1992

Inspector: Thomas F. Young 2/10/93
Thomas F. Young Date
Radiation Specialist

Reviewed By: B. J. Holt 2/10/93
B. J. Holt, Chief Date
Nuclear Materials Inspection
Section 1

Approved By: Roy J. Caniano 2/10/93
Roy J. Caniano, Chief Date
Nuclear Materials Safety Branch

Inspection Summary

Inspection on October 1, 1992 (Report No. 030-10838/92001 (DRSS))
Areas Inspected: This was a routine, unannounced safety inspection conducted to assess the adequacy of the licensee's overall NRC-licensed operation authorized under a limited medical license. The inspection included a review of: organization and management controls, training and instructions to workers, facilities and equipment, personnel radiation exposure monitoring, area survey procedures, sealed source leak tests and inventories, and transportation and waste disposal.
Results: Of the areas inspected, numerous apparent violations were identified, including failure to:

- provide personnel monitoring equipment for a three month period,
- otherwise evaluate personnel radiation exposures during that same period,
- review the radiation safety program annually,

- review aspects of the ALARA program,
- provide training to employees,
- conduct area surveys on weekends after use of licensed material,
- possess appropriate radiation detection survey equipment,
- maintain security or immediate control of the hot lab,
- review and sign records of dose calibrator tests for accuracy, linearity, and geometry dependence,
- review and sign records of sealed source leak tests and sealed source inventories,
- review and sign records of daily and weekly surveys on a monthly basis,
- retain a copy of the Department of Transportation Specification 7A package performance test for the package used to return the Mo-99/Tc-99m generator system to the vendor.

In addition to the numerous apparent violations, an area of concern was also identified. The Radiation Safety Committee members appear to be unfamiliar with pertinent NRC regulations and the conditions of the license, including the model procedures of Regulatory Guide 10.8, Revision 2. The model procedures were to be established and implemented to control the daily operations of NRC-licensed activities.

These apparent violations and the area of concern are indicative of a management breakdown of the radiation safety program for licensed material.

DETAILS

1. Persons Contacted

**Sherri Davidson, Associate Administrator
*B. R. Yalamanchili, M.D., Radiation Safety Officer
Robert Taylor, Director of Medical Imaging
Barb Zornes, Nuclear Medicine Technologist
Lisa Hairston, Nuclear Medicine Technologist

*Denotes attendance at the exit meeting held on October 1, 1992.
**Denotes contact on January 28, 1993.

2. Purpose and Scope of Inspection

This routine, unannounced, safety inspection was conducted to assess the adequacy of Lawrence County Medical Center's NRC-licensed activities that are authorized under a limited scope medical license.

The inspection included: (1) discussions with the licensee's management representatives, Radiation Safety Officer (RSO), and nuclear medicine staff; (2) evaluation of facilities and equipment; (3) independent measurements of radiation exposure rates in the nuclear medicine imaging area and the nuclear medicine hot lab; and (4) review of selected records.

3. Summary of Licensed Program and Inspection History

Lawrence County Medical Center is authorized to possess and use byproduct material specified in 10 CFR 35.100, 35.200 (excluding aerosols), and 35.300 (excluding iodine-131 for thyroid carcinoma) for medical uses; and byproduct material identified in 10 CFR 31.11 for in vitro studies. The licensee conducts a monthly average of 35 diagnostic nuclear medicine procedures consisting primarily of Tc-99m labeled radiopharmaceuticals. The licensee elutes a Mo-99/Tc-99m generator system and prepares radiopharmaceuticals for subsequent administration to the patients. No nuclear medicine therapy treatments are performed. The licensee's RSO is also the principal authorized user.

The NRC inspection conducted on December 3, 1985 identified three violations: (1) failure to follow emergency procedures during a spill of Tc-99m, (2) failure to lock the hot lab or maintain surveillance at all times, (3) failure to amend the license to name a RSO. The NRC inspection conducted on September 28, 1989, identified two violations: (1) failure to perform leak tests of sealed sources on one occasion, and (2) failure to perform dose calibrator linearity tests at quarterly intervals on two occasions.

During the NRC inspection conducted on October 1, 1992, corrective actions were reviewed for each of the above items and were determined to be adequate.

4. Organization and Management Controls

Overall responsibility for the conduct of NRC-licensed activities is vested in the hospital administrator. To oversee the use of byproduct material and implement the radiation safety program, the licensee has established a Radiation Safety Committee (RSC) and appointed a Radiation Safety Officer (RSO) as required.

10 CFR 35.22(b)(6) requires the licensee's RSC to review annually, with the assistance of the RSO, the radiation safety program. A review of the effectiveness of the licensee's oversight indicated that the RSC had not reviewed the radiation safety program annually during the period of September, 1990, to September, 1992. Failure of the RSC to review the radiation safety program annually is an apparent violation of 10 CFR 35.22(b)(6).

10 CFR 35.20(c) requires the licensee to develop and implement a written ALARA program that must include, in part, reviews of: (1) summaries of the types and quantities of uses of byproduct material, and (2) continuing education and training sessions for all personnel who work with or in the vicinity of byproduct material. 10 CFR 35.22(a) requires, in part, that the licensee's RSC meet at least quarterly and the minutes of each RSC meeting must include the ALARA program reviews described in 10 CFR 35.20(c). From a review of the RSC minutes and discussions with the licensee it was determined that although the licensee has an ALARA program, there has not yet been any review of the aforementioned aspects of the program. Failure of the licensee to review the ALARA program is an apparent violation of 10 CFR 35.20(c).

The licensee contracts a medical physics consultant to perform limited radiation safety services, e.g. testing of equipment and reviewing records etc. The licensee's consultant audit reports are sent to the RSO and contain the results of tests and inventories, and additional recommendations for the RSC and RSO, but are not intended to substitute for the RSC and RSO review of the radiation safety program.

Two apparent violations were identified.

5. Training and Instruction to Workers

The NRC inspector verified implementation of the licensee's training commitment by discussing elements of the radiation safety program with the RSC members and the nuclear medicine staff. It was apparent that the RSC members were unfamiliar with pertinent NRC regulations and the conditions of the license, including the model procedures of Regulatory Guide 10.8, Revision 2. Since the RSC has responsibilities for implementation of the radiation safety program, this is an area of concern and an apparent weakness in the licensee's radiation safety program. The nuclear medicine staff seemed to be familiar with general radiation safety procedures, but they also seemed to be unfamiliar with specific NRC requirements.

10 CFR 35.21(a) requires, in part, that the licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for evaluating implementation of the radiation safety program are described in the licensee's application received by NRC on July 6, 1990, and were approved by License Condition No. 15.

The licensee's application received by NRC on July 6, 1990, states in Item 8 that the licensee will establish and implement the model training program that was published in Appendix A of Regulatory Guide 10.8, Revision 2. In addition, ATT 8.1 of the license's application received by NRC on July 6, 1990, identifies the groups of workers who will receive training and the method and frequency of training.

Appendix A of Regulatory Guide 10.8, Revision 2, "Model Training Program," requires the licensee to instruct personnel, including ancillary personnel, in specified subjects at the following intervals: (1) before assuming duties with or in the vicinity of, radioactive material, (2) during annual refresher training, and (3) whenever there is a significant change in duties, regulations, or the terms of the license. In addition, ATT 8.1 of the licensee's application received by NRC on July 6, 1990, requires the licensee to provide monthly training for nuclear medicine staff. The inspector learned that training was not conducted by the licensee on the following occasions: (1) when the license was renewed in its entirety on July 27, 1990, (2) from July 27, 1990, to October 1, 1992, no annual refresher training was provided to personnel, and (3) monthly training for nuclear medicine staff was not conducted since July 27, 1990. Failure of the licensee to provide training to all personnel on the occasions mentioned above is an apparent violation of 10 CFR 35.21(a).

One apparent violation and one area of concern were identified.

6. Facilities and Equipment

10 CFR 35.220 requires, in part, the licensee to possess a portable radiation detection (low range) survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement (high range) survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour. The low range survey instrument in possession of the licensee was designed to detect rates over the range of 0.1 millirem per hour to 50 millirem per hour. In addition, the licensee did not possess a high range survey instrument during two periods that occurred from about January to April, 1991, and from about April to July, 1992. During these two periods, the licensee's high range survey instrument malfunctioned and was eventually replaced. However, the low range survey instrument was calibrated and operable and properly used by the technologist to perform required surveys during these two periods. Failure of the licensee to possess appropriate survey instruments is an apparent violation of 10 CFR 35.220.

Although the licensee did not possess appropriate portable radiation survey instruments at all times, according to the records reviewed by the inspector and the discussions held with the nuclear medicine technologist, there was a calibrated and operable survey instrument in possession of the licensee at all times, and the nuclear medicine technologists appeared to be familiar with the typical radiation exposure rate values and the survey procedures, and no unusual event occurred during the periods when the high range survey instrument was determined to be malfunctioning.

During the October 1, 1992, inspection the licensee possessed a Capintec Model 7 dose calibrator. 10 CFR 35.50(e) requires the licensee to retain records of specific dose calibrator tests, including accuracy, linearity, and geometry dependence. The NRC inspector reviewed the licensee's consultant reports that indicated acceptable results of the dose calibrator tests, as specified in 10 CFR 35.50. However, the RSO's signature was not included with the results of any of the required dose calibrator tests. Failure of the RSO to sign the dose calibrator test results is an apparent violation of 10 CFR 35.50(e).

The inspector visited the licensee's nuclear medicine imaging room where radiopharmaceuticals are administered to patients, and the nuclear medicine hot lab where patient dosages are prepared and assayed prior to administration to the patient. Facilities and equipment were found to be adequate and as stated in the licensee's application for the NRC license. During the tour the inspector performed independent radiation exposure rate measurements throughout the licensee's facilities. The measurements confirmed the values recorded in the records retained by the licensee, with all levels well below 10 CFR Part 20 limits.

10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. On October 1, 1992, the inspector identified licensed material consisting of the Mo-99/Tc-99m generator and Tc-99m imaging agents and dose calibrator standards that were located in the nuclear medicine hot lab which was not secured against unauthorized removal because the door was unlocked and the nuclear medicine staff was not in attendance, and as such the area was not under constant surveillance and immediate control of the licensee. Failure of the licensee to maintain security or constant surveillance and immediate control of the hot lab is an apparent violation of 10 CFR 20.207(a).

The inspector reviewed records of ventilation checks performed in the nuclear medicine imaging room where xenon-133 is administered. The area was found to be at negative pressure as compared to the surrounding rooms. Accordingly the licensee's ventilation checks confirm negative pressure in the area every six months, as required. The inspector

learned that the xenon-133 effluent trap is checked by the nuclear medicine technologist monthly, by collecting an effluent sample during a patient study. The sample is assayed with the gamma camera and compared to an ambient background air sample. According to the technologist, saturation of the xenon-133 effluent trap has not been a problem, however, the most recent effluent sample indicated that the trigger level was nearly exceeded. The technologist indicated that the effluent trap would be replaced in the near future.

Three apparent violations were identified.

7. Personnel Radiation Exposure Monitoring

The NRC inspector reviewed Siemens personnel dosimetry reports for 1991 and 1992, to the date of the inspection. The reported values include personnel dose contribution from x-ray and nuclear medicine. The highest annual radiation dose to personnel during 1991 was 480 millirem, whole body, and 1820 millirem, extremity. The highest values through July, 1992, were 60 millirem, whole body, and 500 millirem, extremity.

10 CFR 35.21(a) requires, in part, that the licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for evaluating implementation of the radiation safety program are described in the licensee's application received by NRC on July 6, 1990, and were approved by License Condition No. 15.

The licensee's application received by NRC on July 6, 1990, states in Item 10.4 that the licensee will establish and implement the model safety rules published in Appendix I of Regulatory Guide 10.8, Revision 2.

Appendix I of Regulatory Guide 10.8, Revision 2, "Model Rules for Safe Use of Radiopharmaceuticals," requires the licensee's employees to wear personnel monitoring equipment at all times while in areas where radioactive materials are used or stored; and to wear a finger exposure monitor during the elution of generators, and during the preparation, assay, and injection of radiopharmaceuticals, and when holding patients during procedures. The records of personnel radiation dosimetry in possession of the licensee indicate that film badges and TLD rings were not provided to nuclear medicine staff from about January 1 to April 1, 1992. During this same period, the nuclear medicine technologists were involved with duties that included elution of generators, and preparation, assay, and injection of radiopharmaceuticals, and holding patients during procedures. The licensee explained that nonpayment was the reason for interruption of the film badge service and the matter was resolved after about three months. The licensee's policy with regard to payment of the film badge vendor was revised to prevent recurrence of interrupted service. Failure of the licensee to furnish film badges and TLD rings to the nuclear medicine staff is an apparent violation of 10 CFR 35.21(a).

10 CFR 20.201(b) requires the licensee to make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. 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. The inspector learned that, as of this inspection, the licensee did not make surveys to assure compliance with those parts of 10 CFR 20.101 that limit radiation exposures to the whole body and to the extremities. Specifically, the licensee did not estimate the occupational radiation doses received by the nuclear medicine personnel during the months of January, February, and March, 1992, when film badges and TLD rings were not furnished to the nuclear medicine staff. Failure of the licensee to evaluate the personnel radiation doses received during the period of January through March, 1992, is an apparent violation of 10 CFR 20.201(b).

During the period when personnel monitoring equipment was not furnished to the nuclear medicine staff, the licensee was in possession of operable and calibrated portable radiation survey instruments i.e. the low range GM type instrument and the high range ionization type instrument. The licensee's records of daily and weekly surveys, and surveys of incoming packages indicated no unusual events e.g. unshielded radioactivity or radioactive spills. Occupational radiation doses received during that period would approximate the occupational radiation dose values reported for similar periods of patient type and quantity. The licensee's personnel radiation dosimetry reports indicated no values in excess of 10 CFR Part 20 limits. It is, therefore, unlikely that the licensee's nuclear medicine technologists received an occupational radiation dose in excess of 10 CFR Part 20 limits.

Two apparent violations were identified.

8. Area Survey Procedures

10 CFR 35.70(a) requires the licensee to survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered. The inspector learned that area surveys are performed at the end of each day's use, however, area surveys are not routinely performed during weekends when the technologist is called to perform an emergency imaging procedure. According to the licensee's statements, at least four emergency imaging procedures were performed during the period of January 6 to October 1, 1992. Failure to perform daily surveys at the end of the day is an apparent violation of 10 CFR 35.70(a). Weekly wipe test surveys are performed as required. Review of the records of daily surveys and weekly wipe test surveys revealed no radiation dose rates in excess of 10 CFR Part 20 limits, or removable radioactive contamination in excess of ambient background counts from the gamma camera detector that is used to assay the wipe test samples.

10 CFR 35.21(a) requires the licensee, through the RSO, to ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for area surveys are described in the application received on July 6, 1990, and were approved by License Condition No. 15.

The licensees application received on July 6, 1990, states in Item No. 10.12 that the licensee will establish and implement the model procedure for area surveys that was published in Appendix N of Regulatory Guide 10.8, Revision 2.

Appendix N of Regulatory Guide 10.8, Revision 2 ,"Model Procedure for Area Surveys," requires the licensee's RSO to review and initial the survey records at least monthly and also promptly in those cases in which action levels were exceeded. Records in possession of the licensee and conversations with the licensee during the inspection indicated that as of October 1, 1992, the RSO did not routinely review and sign or initial the records. Failure of the licensee, through its RSO, to review and sign or initial the survey records on at least a monthly basis is an apparent violation of 10 CFR 35.21(a).

Two apparent violations were identified.

9. Sealed Source Leak Tests and Inventories

10 CFR 35.59(d) and (g) require the licensee to maintain records of sealed source leak tests and inventories that include the signature of the RSO. The NRC inspector reviewed licensee consultant reports that indicate the results of sealed source leak tests and physical inventories. The reports are received and reviewed by the RSO. The RSO's signature is not included with the results of sealed source leak tests and physical inventories. Failure of the RSO to sign the results of sealed source leak tests and physical inventories is an apparent violation of 10 CFR 35.59(d) and (g).

One apparent violation was identified.

10. Transportation and Waste Disposal

The licensee returns a Mo-99/Tc-99m generator to the vendor each week. All other radioactive waste is decayed in storage. The licensee maintains a receipt and disposition log that includes the information required by 10 CFR 35.92. The licensee follows the vendor's instructions for returning the Mo-99/Tc-99m generators. The nuclear medicine technologist re-packages the generator for return to the vendor by using the same packaging materials in which the generator was previously received from the vendor. 10 CFR 71.5(a) requires the licensee to comply with the appropriate regulations of the Department of Transportation in 49 CFR 170-189. 49 CFR 173.415(a) requires the licensee to retain for one year after the latest shipment, a copy of the Department of Transportation Specification 7A package performance test record. The licensee did not possess a copy of the performance test

record for the package that is used to return the Mo-99/Tc-99m generator systems to the vendor. Failure of the licensee to possess a copy of the Department of Transportation Specification 7A package performance test record is an apparent violation of 10 CFR 71.5(a) and 49 CFR 173.415(a).

One apparent violation was identified.

11. Other Areas Inspected

In addition to the specific areas described in this report, the inspector also reviewed the licensee's current inventory of radioactive material, procedures for ordering and receiving and safely opening packages of radioactive material, survey records for incoming packages, notification and reports to workers, records of Mo-99 breakthrough tests, misadministrations, bulletins and information notices received from NRC, and proper posting and labeling.

No violations of NRC requirements were identified.

12. Exit Meeting

On October 1, 1992, the inspector held an exit meeting with the RSO to discuss the preliminary inspection findings, NRC Enforcement Policy, and the licensee's preliminary corrective actions. On January 28, 1993, the apparent violations were discussed between Mr. Roy Caniano of the NRC and Sherri Davidson, Associate Administrator for the licensee.