

U. S. NUCLEAR REGULATORY COMMISSION

REGION II

Docket No.: 030-33303

License No.: 45-25272-01

Report No.: 45-25272-01/97-01

Licensee: Southeastern Imaging

Location: Martinsville, Virginia

Date: March 3, 1997

Inspector: Wade T. Loo, Health Physicist

Approved by: Thomas R. Decker, Acting Chief
Materials Licensing/Inspection Branch 1
Division of Nuclear Materials Safety

Enclosure 2

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EXECUTIVE SUMMARY

Southeastern Imaging
NRC Inspection Report 45-25272-01/97-01

This routine, unannounced inspection included discussions with cognizant licensee representatives, reviews of documents, and direct observations of licensed activities. The inspection included a review of management oversight, organization and scope of the program, facilities, equipment and instrumentation, training, retraining and instruction to workers, area radiation detection surveys and contamination surveys, personnel radiation protection, radioactive waste management, transportation, posting and labeling, and miscellaneous issues. The report covers operations conducted by the licensee between June 30, 1994, and March 3, 1997.

Management Oversight

- The licensee had maintained adequate management oversight of the radiation safety program through the efforts of a health physics consultant to ensure compliance to NRC regulatory requirements and the licensee's license and application.

Organization and Scope of the Licensee Program

- Licensed materials were used for mobile nuclear medicine activities. The organization of those areas was found adequate and in accordance with the licensee's license application. Efforts by the Radiation Safety Officer with regards to radiation safety were adequate to ensure compliance to NRC regulatory requirements and the licensee's license and application.

Facilities

- The inspector identified a violation of NRC regulatory requirements regarding the storage of the mobile nuclear medicine unit (MNMU) at a temporary location not authorized on the licensee's license.
- The licensee conducted licensed activities in a MNMU. The inspector observed the MNMU facilities and determined that they were adequate for conducting licensed activities authorized by the licensee's license and application.

Equipment and Instrumentation

- Equipment and instrumentation used and maintained by the licensee was found to be properly tested and calibrated in accordance with NRC regulatory requirements, and users were found knowledgeable in the use of the instrumentation.

Training, Retraining, and Instructions to Workers

- Licensee personnel were trained in accordance with 10 CFR Part 35 and 19.12, and radiation workers had received the minimum instructions commensurate with their involvement in licensed activities.

Area Radiation Surveys and Contamination Surveys

- The inspector identified a violation of NRC regulatory requirements regarding area radiation surveys of the MNMU in that on numerous occasions those surveys had not been conducted.
- The handling of isotopes was reviewed by the inspector and was found to be in accordance with the licensee's procedures and standard practices. Leak tests and inventories were found to have been conducted in accordance with NRC regulatory requirements.

Personnel Radiation Protection

- The licensee's monitoring program was found to be adequate. No overexposures were identified, and the licensee's As Low As Reasonably Achievable (ALARA) practices was reviewed by the inspector and appeared to be adequate in reducing radiation exposures to licensee personnel.

Radioactive Waste Management

- The inspector found that the licensee adequately maintained radioactive material waste for decay-in-storage and/or properly disposed of that waste in accordance with NRC regulatory requirements and the licensee's license and application.

Transportation

- The inspector observed that transportation activities involving licensed materials were conducted in accordance with NRC and Department of Transportation regulatory requirements.

Posting and Labeling

- Areas of radioactive material use were observed by the inspector and found to be properly posted/labeled and radiation hazards clearly identified to demonstrate compliance to NRC regulatory requirements.

Miscellaneous Issues

- The inspector found that the licensee had corrected a previous violation wherein the licensee failed to conspicuously note the apparent exposure rate from a dedicated check source as determined at the time of survey meter calibration on a survey instrument used by the licensee.

REPORT DETAILS

01. Management Oversight (87100)

Through discussions with cognizant licensee representatives and a review of radiation safety program audit records from June 30, 1994, to the date of the onsite inspection, the inspector determined that the licensee contracted with a health physics consultant (HPC) to conduct quarterly audits of the radiation safety program. From those reviews and discussions, the inspector determined that the consultant reviewed radiation safety records for nuclear medicine activities to include radiation surveys, inventory, radioactive waste disposal, and instrument quality control checks. The inspector noted that the consultant had conducted quarterly audits of the radiation safety program, and did not identify any significant findings of noncompliance with regards to the procedures and practices conducted under the licensee's NRC license. In addition to those reviews, the licensee's Radiation Safety Officer (RSO) would conduct reviews as discussed below in Paragraph 02. Based on those discussions and reviews, the inspector concluded that the licensee was conducting adequate audits of the radiation safety program relative to the activities conducted by the licensee under their NRC byproduct materials license.

02. Organization and Scope of the Licensee Program (87100)

The inspector reviewed selected records from June 30, 1994, to the date of the onsite inspection, and discussed with licensee representatives the organization and program activities associated with the license. From those discussions and reviews the inspector determined that the licensee used a mobile nuclear medicine unit (MNMU) to conduct various nuclear medicine activities. Nuclear Medicine activities involved the use of radiopharmaceuticals for diagnostic purposes. This included the use of technetium-99m labeled radiopharmaceuticals for routine diagnostic studies such as bone, lung, and heart scans. The licensee received those radiopharmaceuticals from a nuclear pharmacy. Up until a few months ago, the licensee utilized the same MNMU for activities in another state under an Agreement State license concurrent with activities conducted under the licensee's NRC license. The licensee would rotate the use of the MNMU from one facility to another and from state to state. However, the licensee recently purchased another MNMU allowing one MNMU to be used strictly for activities conducted under their Agreement State license and one MNMU for those activities conducted under their NRC license. When the licensee possessed only one MNMU, the licensee maintained two sets of policies and procedures, one set specific for each license. The results of equipment tests and checks, and radiation surveys were combined and maintained on the same set of records for those activities conducted under the licensee's Agreement State and NRC licenses. As a result of recent personnel changes and Agreement State activities, at the time of the onsite inspection the licensee was in the process of changing their policies and procedures to incorporate those records maintained for both licenses into one set of procedures and policies. As a result of the proposed

policy and procedure changes, the licensee believed that they would be able to document their activities in a more manageable and efficient manner. In addition, the licensee employed two nuclear medicine technologists, one dedicated for each MNMU.

The licensee's RSO maintained oversight of all radiation safety activities at the licensee's facility. The RSO was responsible for reviewing HPC audits, the inventory of radioactive material possessed by the licensee, survey instrument calibrations, dose calibrator tests and checks, leak tests of sealed sources, personnel radiation exposures, and radioactive waste management. Also, the licensee's RSO was the president of the company and an authorized user. Since the last onsite inspection, the licensee had several changes in personnel with regards to the nuclear medicine technologist who performed the day-to-day clinical procedures and radioisotope handling.

Based on those discussions and reviews, the inspector concluded that the licensee was making adequate changes to the radiation safety program to ensure compliance to NRC regulatory requirements, license and application.

03. Facilities (87100)

Through discussions with cognizant licensee representatives and direct observations made by the inspector, the inspector determined that the MNMU used for NRC activities had one imaging camera. Radioactive material, including sealed sources and diagnostic radiopharmaceuticals, were maintained and locked in the MNMU.

Through discussions with licensee representatives, the inspector determined that the licensee had previously stored the MNMU at one of the authorized hospital locations considered a temporary job site. However, the licensee within the last month of the date of the onsite inspection had employed a new driver who on February 27, 1997, stored and maintained the MNMU at his private residence located on Route 1, Henry, Virginia. License Condition No. 10.A requires, in part, that licensed material be used only in the licensee's MNMU located on the property of RJ Reynolds Patrick Memorial County Hospital, Stuart, Virginia, Bedford County Memorial Hospital, Bedford, Virginia or at other temporary job locations of the licensee throughout the Commonwealth of Virginia. Failure to store and maintain the MNMU at an authorized location of use was identified as a violation (VIO) of License Condition No. 10.A (VIO 030-33303/97001-02).

Through discussions with licensee representatives and direct observations made by the inspector, the inspector determined that the licensee had conducted licensed activities in the MNMU. Based on those discussions and direct observations, the inspector concluded that the facilities observed during the onsite inspection were the same as those described in the licensee's NRC license and application material. In addition, the inspector found the facilities to be adequate for conducting those activities authorized by the license.

04. Equipment and Instrumentation (87100)

04.1 Dose Calibrator

The inspector reviewed selected dose calibrator records from June 30, 1994, to the date of the onsite inspection and discussed those records with cognizant licensee representatives. The inspector determined that the licensee had one dose calibrator. In addition, the inspector determined that the licensee had conducted linearity tests, accuracy tests, geometry dependence tests and constancy checks for the dose calibrator since the date of the last onsite inspection. Because they utilized a MNMU that changed locations of use, the licensee conducted those tests each time they arrived at a different location and prior to use to ensure that the instrument operated in accordance with NRC regulatory requirements, and the license and application. Based on those reviews and discussions, the inspector did not observe any measurements or results that exceeded NRC regulatory requirements or would have necessitated repair of the instrument. Also during the onsite inspection, the inspector discussed with licensee personnel the procedures for conducting dose calibrator checks. Based on those reviews, and discussions, the inspector concluded that the licensee had conducted adequate tests and checks on the dose calibrator to ensure that it operated and measured radiopharmaceuticals accurately.

04.2 Radiation Detection Instrumentation

The inspector reviewed radiation detection instrumentation records from June 30, 1994, to the date of the onsite inspection, and discussed those records with cognizant licensee representatives. From those reviews, discussions, and direct observations, the inspector determined that the licensee possessed two radiation detection survey instruments located in the MNMU. Those instruments observed by the inspector were capable of detecting dose rates over the range of 0.1 millirem per hour (mrem/hr) to 100 mrem/hr and 1 mrem/hr to 1,000 mrem/hr. Through further discussions, reviews and direct observations, the inspector determined that the licensee possessed a well counter used to count removable contamination survey samples of the MNMU. From those reviews and discussions, the inspector determined that the instrument was capable of detecting contamination to 2,000 disintegrations per minute/100 cm². During the onsite inspection, the inspector discussed with cognizant licensee personnel the procedures for conducting radiation detection surveys and observed those individuals demonstrate how to source check the survey instruments. From those reviews, discussions and observations, the inspector concluded that the licensee maintained calibrated radiation detection instruments and that licensee personnel conducted source checks adequately to ensure that the instruments were capable of detecting those radiation levels described in 10 CFR Part 20. In addition, the inspector conducted independent

radiation detection surveys for contamination and did not identify any areas above background. Furthermore, the survey results identified by the inspector were consistent with those made by the licensee.

05. Training, Retraining, and Instructions to Workers (87100)

During the onsite inspection, the inspector discussed with cognizant licensee representatives radiation safety training given to licensee personnel and reviewed those topics discussed. From reviews and discussions with cognizant licensee personnel, the inspector determined that the licensee's RSO had conducted informal training for licensee employees. However, the licensee's HPC conducted the licensee's formal training which included good radiation safety practices and precautions, use of protective equipment and dosimetry, and updates in radiation safety and events. From those reviews and discussions with licensee personnel, the inspector determined that the licensee was adequately instructing personnel in radiation safety and those activities associated with the NRC byproduct material license in accordance with NRC regulatory requirements.

06. Area Radiation Surveys and Contamination Control (87100)

06.1 Area Radiation and Contamination Surveys

The inspector reviewed selected area radiation detection survey records conducted from June 30, 1994, to the date of the onsite inspection, and discussed those records with cognizant licensee representatives. From those reviews and discussions, the inspector determined that the licensee had not conducted area radiation surveys on 5 occasions between June 30, 1994, and March 3, 1997, when millicurie quantities of technetium-99m labeled radiopharmaceuticals had been used in the MNMU. Specifically, the licensee did not conduct those surveys on September 23, October 5, and December 7, 1996, and January 30, and March 1, 1997. 10 CFR 35.70(a) requires that a licensee 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. Failure to conduct surveys with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals were routinely prepared for use or administered was identified as a VIO of 10 CFR 35.70(a) (VIO 030-33303/97001-01).

06.2 Leak Tests and Inventories

The inspector reviewed selected sealed source leak tests and inventory records conducted from June 30, 1994, to the date of the onsite inspection, and discussed those records with cognizant licensee representatives. Through those discussions and reviews, the inspector determined that sealed source leak tests and the quarterly inventories were conducted by the licensee's HPC. From

a review of records, discussions, and observations, the inspector independently verified that the licensee had adequately conducted sealed source leak tests and inventories since the last onsite inspection. The inspector found that the licensee had conducted those activities in accordance with NRC regulatory requirements.

07. Personnel Radiation Protection (83822)

The inspector reviewed selected radiation exposure dosimetry records from June 1994 to December 1996, and discussed those records with cognizant licensee representatives. From those reviews and discussions, the inspector determined that licensee personnel involved with NRC licensed activities were issued film badges and finger rings and exchanged the dosimetry on a monthly frequency. For the calendar year 1996, the highest total effective dose equivalent (TEDE) whole body and extremity exposure an individual received was 130 and 300 mrem, respectively. During the onsite inspection, the inspector observed licensee personnel wearing radiation dosimetry appropriately to detect radiation exposures from the handling and use of radioactive material at the licensee's facility. Based on those reviews, discussions, and direct observations, the inspector determined that the licensee was maintaining personnel radiation exposures ALARA and no NRC regulatory radiation exposure limit had been exceeded for licensee personnel.

08. Radioactive Waste Management (87100)

The inspector reviewed selected radioactive waste records for nuclear medicine activities from June 30, 1994, to the date of the onsite inspection, and discussed those records with cognizant licensee personnel. From those discussions and reviews, the inspector determined that the licensee stored radioactive waste in the MNMU. The licensee held the radioactive waste for storage-in-decay for periods that were greater than 10 half-lives. After 10 half-lives the licensee conducted radiation surveys to ensure that the waste was at or below background and disposed of the waste as biohazard trash. With regards to radiopharmaceutical waste, the licensee had an agreement with the nuclear pharmacy regarding used and unused radiopharmaceuticals. The nuclear pharmacy delivered radiopharmaceuticals to the licensee's office location in Martinsville, Virginia. After delivering the radiopharmaceuticals the nuclear pharmacy would take possession of used and unused radiopharmaceuticals for disposal at their facility. In addition, the inspector observed the radioactive waste area maintained by the licensee. The inspector conducted area radiation detection surveys and did not observe any area radiation levels that would cause a member of the public to exceed any NRC regulatory radiation exposure limits. Based on those reviews, discussions and observations, the inspector concluded that the licensee adequately maintained radioactive waste at the licensee's facility in accordance with NRC regulatory requirements.

09. Transportation (86740)

The inspector reviewed selected transportation records from June 30, 1994, to the date of the onsite inspection and discussed those records with cognizant licensee representatives. From those reviews and discussions, the inspector determined that the licensee received diagnostic radiopharmaceuticals from a nuclear pharmacy at the licensee's Martinsville, Virginia office location. The licensee would then leave that office location and drive to that day's designated hospital to conduct licensed nuclear medicine activities. Based on those reviews, discussions, and direct observations, the inspector concluded that radiopharmaceutical receipt from and transfer to the nuclear pharmacy, and transportation to and from hospitals had been conducted in accordance with DOT and NRC regulatory requirements.

10. Posting and Labeling (87100)

During the onsite inspection, the inspector observed that those areas within the licensee's MNMU where radioactive material was used had been adequately posted with appropriate radiation postings to warn individuals of the radiation hazards associated with those areas. Also, the inspector observed that sealed and unsealed sources, radiopharmaceuticals, and waste containers had appropriate labels to identify the radioactive materials in them. In addition, the inspector independently verified that NRC Form-3 and notices referencing the appropriate 10 CFR Parts 19, 20, and 21, and licensee documents were posted in accordance with the applicable regulation. Specifically, the inspector observed that the documents were posted on a wall in the MNMU. Based on those observations, the inspector concluded that the licensee had adequately posted areas and labeled radioactive materials in accordance with NRC regulatory requirements.

11. Miscellaneous Issues (92702)

(Closed) Non Cited Violation (NCV) 030-33303/94001-01: Failure to have apparent exposure rate from a dedicated check source as determined at the time of survey meter calibration on the survey instrument.

The inspector determined by records review that the NCV had been corrected after the conclusion of the June 1994, inspection. In addition, the inspector independently verified through direct observations that current survey instruments used by the licensee included the apparent exposure rate as per 10 CFR 35.51(a)(3). Based on those reviews and observations the inspector confirmed that the violation had not recurred since the date of the last onsite inspection.

EXIT MEETING SUMMARY

The inspector presented the inspection results to licensee representatives at the conclusion of the inspection on March 3, 1997. The inspector informed those licensee representatives present that two violations of NRC regulatory requirements had been identified regarding the failure to conduct area radiation surveys at the end of each day of use for areas where radiopharmaceuticals were routinely prepared for use or administered in the mobile nuclear medicine unit and storing the mobile nuclear medicine unit at a temporary location not authorized by the license. The licensee acknowledged those inspection findings. Licensee representatives did not identify any documents or processes as proprietary in nature. Dissenting comments were not received from the licensee.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

- *N. Bhatt, M.D., President, RSO
- *T. Radford, Driver/Manager
- *J. Sizemore, Vice-President of Clinical Services
- *K. Stone, Nurse Consultant
- *K. Zseltvay, Vice-President of Operations

*Attended March 3, 1997, Exit Meeting

INSPECTION PROCEDURES USED

IP 87100:	Licensed Materials Program
IP 83822:	Radiation Protection
IP 86740:	Inspection of Transportation Activities
IP 92702:	Followup on Corrective Actions for Violations and Deviations

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-33303/97001-01	VIO	Failure to conduct surveys with a radiation detection survey instrument at the end of each day of use for areas where radiopharmaceuticals were routinely prepared for use or administered.
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030-33303/97001-02 VIO Failure to store the MNMU at a temporary location not authorized by the licensee's license.

Closed

030-33303/94001-01 VIO Failure to conspicuously note the apparent exposure rate from a dedicated check source as determined at the time of survey meter calibration on a survey instrument.