U.S. NUCLEAR REGULATORY COMMISSION

REGION II

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Licensee:	Department of the Army Dwight D. Eisenhower Army Medical Center
Location:	Fort Gordon, Georgia
Inspection Date:	December 8, 1998
Inspectors:	David J. Collins, Radiation Specialist Richard Gibson, Jr., Radiation Specialist
Approved by:	Mark S. Lesser, Chief Materials Licensing/Inspection Branch 2 Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Dwight D. Eisenhower Army Medical Center
Fort Gordon, Georgia
NRC Inspection Report No. 10-12044-03/98-01

A routine safety inspection was conducted on December 8, 1998, at the licensee's facility located at Fort Gordon, Georgia. The inspection included interviews with licensee representatives, selective examination of records, and direct observation of licensed activities. Areas inspected were: review of management oversight; organization and scope of licensee program; facilities; equipment and instrumentation; training, retraining and instruction to workers; area radiation and contamination controls; personnel radiation protection; radioactive waste management; and posting and labeling. The report covers operations conducted by the licensee from January 16, 1996 to December 1998.

The licensee's management, up to and including the executive level, appears to be directly involved with the radiation safety program, and the Radiation Safety Committee. The licensee's organizational structure for the possession and use of licensed material was determined to be appropriate to support the licensed activities and ensure the safe use of radioactive materials. The facilities are adequate for the safe possession and use of licensed material and the licensee's equipment and instrumentation used were adequate, operable, calibrated and maintained. Training adequately addressed all aspects of the radiation safety program.

Area radiation surveys and laboratory contamination controls conducted by the licensee were adequate and met the license and NRC regulatory requirements. The licensee maintains personnel radiation exposures ALARA and NRC regulatory radiation exposure limits have not been exceeded. The licensee maintains its waste management program adequately and in accordance with license commitments and NRC regulatory requirements.

The Nuclear Pharmacy, Nuclear Medicine and the Health Physics staff were knowledgeable and trained in the licensee's operation policies and safety procedures. There were no misadministrations since the last inspection.

REPORT DETAILS

1. Management Oversight (87119)

a. Scope

The inspectors interviewed knowledgeable licensee representatives, and reviewed licensee records, to understand the licensee's management oversight in order to determine whether the organization and staffing were as required by the license and commensurate with the complexity of the radiation safety program.

b. Observations and Findings

Through interviews with cognizant licensee representatives and review of records, the inspectors determined that the licensee's executive management are actively involved with the radiation safety program. The radiation safety staff consists of a Radiation Safety Officer (RSO), a Non-Commissioned Officer-in-Charge, and civilian radiation safety personnel. The radiation safety staff performs quarterly and annual audits of the radiation safety program, performs inventory and leak testing of sealed sources, manages the licensee's radioactive waste program, conducts training of radiation workers. Survey instruments are sent to Redstone Arsenal, Alabama for calibration.

The licensee's Radiation Safety Committee (RSC) reviews and approves authorized users and the protocols proposed for the use of radioactive materials. The RSC also evaluates the adequacy of laboratories where radionuclides are used, reviews all aspects of licensed activities, and investigates incidents as necessary. The RSC conducted the final review of the implementation of corrective actions to achieve compliance regarding items identified during the internal auditing process. The RSO compiles a radiation safety program status report every quarter and provides the information to the RSC.

Use of byproduct material is conducted by the licensee in nuclear medicine and in research. In nuclear medicine, licensed material is used by and/or under the supervision of one full time radiologist who has met NRC regulatory training requirements and the license application, an Authorized Nuclear Pharmacist, a Technical Director of Nuclear Medicine and four nuclear medicine technologists. In addition, there are nuclear medicine technologists from Medical College of Georgia who rotate in nuclear medicine. In research, there are no active principal investigators. There are qualified authorized users who are authorized to possess licensed material and conduct licensed activities in the laboratories.

c. Conclusions

The licensee's organization and staffing were as described in the license application. Management appears to be directly involved with the radiation safety program, and the RSC.

2. Organization and Scope of Licensee Program (87119)

a. Scope

The inspectors reviewed the licensee's activities to determine whether the quantities of materials possessed and activities were as authorized in the license. The licensee is authorized to possess and use any medical radiopharmaceutical identified in 10 CFR 35.100 and 200, any therapeutic radiopharmaceutical identified in 10 CFR 35.300 , and licensed material used for in vitro testing identified in 10 CFR 31.11. The licensee is also authorized to possess and use licensed material for research and development including animal studies. These activities are authorized at the licensee's facilities located at Dwight D. Eisenhower Army Medical Center, Fort Gordon, Georgia.

b. Observations and Findings

During the inspection, the inspectors observed the licensee perform several diagnostic imaging procedures using an average of 25 millicuries (mCi) of technetium 99m (Tc-99m). The inspectors also observed the administration of Tc-99m. The Authorized Nuclear Pharmacist usually injects licensed materials. The licensee also performs cardiac imaging. The licensee also performs therapeutic procedures to patients using phosphorus 32 (P-32), strontium 89 (Sr-89), iodine 131 (I-131) and on occasion, samarium 153 (Sm-153). According to the licensee, the amount of activity for therapeutic treatment to patients can range from 3 millicuries up to 200 millicuries and the patient is kept in the hospital. The licensee stated that the maximum therapeutic treatment performed by them was 100 millicuries of I-131 for the thyroid. There were no therapeutic procedures performed by the licensee during this inspection. The inspectors determined through observation and discussion with licensee representatives that the nuclear medicine technologists used good techniques and safety measures in their administering of radioactive material to patients.

In research, the licensee's RSC authorized the use of radioactive material to principal investigators. At the time of this inspection, there were no experiments using radioactive material with animals during this inspection. The individuals were knowledgeable and understood the requirements of the radiation safety program.

The inspectors reviewed records from January 1996 to December 8, 1998, and discussed with licensee representatives the organization and program activities under the license. The inspectors reviewed records of the RSC minutes for the dates 1996 through 1998. Records were as required and there were no issues of radiation safety concerns. In addition, records of the Radiation Safety Program Annual Report were reviewed for the calendar years 1996 thru 1997. Reviews of the content and implementation of the radiation safety program by the licensee were as required.

c. Conclusions

The licensee conducted activities in accordance with the license conditions and NRC regulatory requirements. In addition, the licensee's organizational structure for the possession and use of licensed material was appropriate to support the licensed activities and ensure the safe use of radioactive materials.

3. Facilities (87119)

a. Scope

The inspectors reviewed the licensee's facilities to determine if they were as described in the license application and if they were adequate for conducting activities authorized by the license.

b. Observations and Findings

The inspectors toured the Nuclear Medicine Department and the radiopharmaceutical therapy patient room on Ward 9 West, and interviewed various nuclear medicine technologists and nursing personnel. The inspectors determined that areas where licensed materials were received, used, and stored were as described in the license application and in conformance with NRC regulatory requirements.

In Nuclear Medicine, the inspectors observed that doors to the area and the hot lab were either locked when not occupied or attended by one or more of the trained staff members. Access to the hot lab and the research department was by a combination or key. Radioactive material and waste were appropriately stored and secured when not in use, preventing unauthorized removal or access.

c. Conclusions

The inspectors determined that the licensee facilities were as described in the license application. In addition, the facilities were adequate for the safe possession and use of licensed material.

4. Equipment and Instrumentation (87119)

a. Scope

The inspectors interviewed licensee personnel, reviewed records and observed equipment and instrumentation to determine whether they were adequate for conducting activities authorized by the license.

b. Observations and Findings

The inspectors determined that the licensee possesses two Capintec dose calibrators, Models 35R and 12R. Daily constancy, quarterly linearity and annual

accuracy checks were performed as required for the dose calibrator. Records of constancy were reviewed for the dates from January 1996 to December 1998. Records were as required by the license application and NRC regulatory requirements. Constancy of the dose calibrator was checked with a sealed cesium 137 (Cs-137). Records of linearity were reviewed for the dates from February 1996 to October 1998. Records were as required by the license application and NRC regulatory requirements. Performance of the dose calibrator was linear down to less than 30 μCi. Records of accuracy were reviewed for the dates from January 1996 to July 1998. Geometry dependence of the dose calibrator was checked by the licensee appropriately at receipt. The dose calibrator was performing accurately, within specified limits.

The licensee also possesses several radiation detection instruments located in nuclear medicine, research laboratories and in the office of the RSO. Survey instruments are calibrated by the calibration service at Redstone Arsenal Alabama. In addition, the licensee performs daily survey instrument checks with the attached cesium-137 check source mounted on the instrument.

c. Conclusions

The licensee's equipment and instrumentation used were adequate, operable, calibrated, and maintained.

5. Training, Retraining, and Instructions to Workers (87119)

a. Scope

The inspectors interviewed several individuals, observed actual work performed using licensed material, and discussed radiation safety training with the licensee to determine whether the training program was in accordance with 10 CFR Parts 35 and 19.12, and to determine whether ancillary personnel received instructions commensurate with their involvement with licensed activities.

b. Observations and Findings

Individuals in nuclear medicine and in research are trained in radiation safety prior to radioactive material use and annually thereafter. Training is conducted by the licensee's radiation safety staff. Ancillary personnel receive instructions in radiation safety that is provided by the radiation safety staff during annual in-service training. Records of in-service training were reviewed for the years 1996 thru 1998. Training records were as required by the license application and NRC regulatory requirements.

c. Conclusion

Radiation safety training and instruction to support personnel were provided by the licensee in accordance with the license application and NRC regulatory requirements. The training adequately addressed all aspects of the radiation safety program.

6. Area Radiation Surveys and Contamination Control (87119)

a. Scope

The inspectors reviewed records of surveys for removable radioactive contamination and radiation levels in all areas where radioactive material is routinely prepared for use, administered, and stored. Records of daily radiation and weekly contamination surveys were reviewed for the dates from 1997 thru 1998. The records were as required by the license application and NRC regulatory requirements. Weekly contamination surveys and radiation surveys are conducted in all areas where radioactive material is routinely prepared for use, administered, and stored.

b. Observations and Findings

Through interview and observation, the inspector determined that a newly installed computer system was being used in the Nuclear Pharmacy. Current records are maintained on the new system. Past recordkeeping is maintained on the previous computer system. The inspectors also reviewed leak test procedures and records, and determined that there were no discrepancies.

The inspectors performed independent radiation surveys in the hot lab, stress and camera areas, patient waiting room and the general areas of nuclear medicine. In addition, independent radiation and contamination surveys were performed in several laboratories in the research department. Survey instruments used by the inspectors were a Ludlum Model 2401, NRC serial No. 013080G, last calibrated on February 26, 1998, an Eberline Model E-120, NRC serial No. 019647, last calibrated on February 17, 1998, and a Ludlum Model 2401-P, NRC serial No. 069356, last calibrated on September 28, 1998. Radiation measurements indicated levels of < 0.1 mrem/hr in the general areas and the stress areas in nuclear medicine, 0.1 to 0.5 mrem/hr in the sealed source storage area of the hot laboratory, and approximately 0.2 mrem/hr in the patient waiting room of nuclear medicine. Radiation and contamination levels were less than the licensee's trigger levels for decontamination in the research department. Typically, spent generators are kept at the facility for 5-6 weeks, then returned to the vendor for salvage.

Records of package receipt and return surveys were reviewed for both nuclear medicine and research, for the dates from January 1996 to June 1998. Records were as required by the license application and NRC regulatory requirements. The inspectors determined that the licensee is performing the required radiation

and contamination level surveys for package receipt and the returning of packages to the vendor.

c. Conclusion

The inspectors determined that area radiation surveys and laboratory contamination controls conducted by the licensee were adequate and met the license and NRC regulatory requirements.

7. Personnel Radiation Protection (87119)

a. Scope

The inspectors reviewed the licensee's program for monitoring occupational radiation doses to determine whether it met regulatory requirements. The inspectors reviewed radiation exposure records for the dates 1996 through 1998. The records were discussed with licensee personnel to determine if the licensee was meeting limits specified in 10 CFR 20 and their ALARA commitment.

b. Observation and Findings

Through interviews and observation, the inspectors determined that the licensee personnel were issued whole body and extremity dosimetry as required, and the dosimetry was exchanged on a monthly basis from the dosimetry service at Redstone Arsenal, Alabama. In addition, thyroid monitoring was performed by the licensee as required by the license application and NRC regulatory requirements. The inspectors determined that no measurable uptake of radioiodine had occurred. The maximum whole body dose (TEDE) reviewed was approximately 460 mrem/year and the maximum extremity dose was approximately 480 mrem/year. The inspectors observed licensee personnel wearing appropriate dosimeters during the handling and administration of radioactive material at the facility.

c. Conclusions

The licensee's program for monitoring workers' external and internal exposures met NRC regulatory requirements. The inspectors determined that the licensee was maintaining personnel radiation exposures ALARA and that no NRC regulatory radiation exposure limits had been exceeded.

8. Radioactive Waste Management (87119)

a. Scope

The inspectors reviewed licensee waste records, interviewed licensee staff and toured the waste handling and packaging facilities, to determine whether the radioactive waste management program complies with license conditions and meets regulatory requirements.

b. Observations and Findings

Radioactive waste generated by the licensee is handled and processed by the Health Physics staff. The inspectors reviewed waste disposal records for the dates from February 3, 1996 to August 14, 1998. Records were as required by the license application and NRC requirements.

The licensee is authorized to dispose of radioactive waste in several ways. Radioactive material with a half-life of less than 65 days is held for decay-in-storage before disposal as ordinary trash after being properly surveyed. Radioactive waste from nuclear medicine is disposed as bio-hazardous waste after decay to ten half-lives and is properly surveyed by the licensee.

c. Conclusions

The inspectors determined that the licensee maintains its waste management program in accordance with license commitments and regulatory requirements.

9. Posting and Labeling (87119)

a. Scope

The inspectors reviewed the licensee's program for posting requirements and the NRC Form 3 "Notice to Workers" to determine whether they met NRC regulatory requirements.

b. Observations and Findings

The inspectors toured nuclear medicine, the therapy patient room and the research facility and found that the licensee had adequately posted and labeled room doors, storage containers and equipment with the required postings. In addition, the inspectors noted that containers for solid waste packaged for disposal and containers for spent radiopharmaceuticals were properly packaged and labeled for transportation. There were no labels or posting problems identified by the inspectors while touring nuclear medicine and the research laboratories.

c. Conclusion

The inspectors determined that the licensee's posting requirements and notices to workers were as required by the NRC regulatory requirements.

EXIT MEETING SUMMARY

An exit meeting was held with licensee representatives on December 8, 1998. The overall findings from the inspection, including their corrective actions from a previous violation were discussed. The licensee reiterated the strong commitment towards the support of the radiation safety program and compliance with NRC regulatory requirements. The licensee did not specify any information reviewed during the inspection as proprietary in nature.

ATTACHMENT

1. PERSONS CONTACTED

Licensee

*Robert J. Kaminski, MD, COL MC; Chief Nuclear Medicine
*Mark D. Kreuger, CPT MS; Chief, Nuclear Pharmacy
*C. David Krivanek, DAC; Technical Director Nuclear Medicine
*Walter J. Moore, MD, COL MC; Deputy Commander for Clinical Services
*Davis A. Rubenstein, LTC, MS; Deputy Commander for Administration
*Louie Tonry, MAJ, MS; Chief, Health Physics and Radiation Safety Officer
*Michael Morgese, SSG; Alternate Radiation Safety Officer

*Attended the December 8, 1998 Exit Meeting

In addition, various nuclear medicine technologists and custodial management were interviewed during the inspection.

2. INSPECTION PROCEDURE USED

IP 87119 Medical Broad-Scope Programs

3. ABBREVIATIONS USED

ALARA	as low as reasonably achievable
Cs-137	cesium 137
dpm/cm^2	disintegrations per minute per centimeter squared
H-3	hydrogen 3, tritium
mCi	millicurie
mrem/hr	millirem per hour
P-32	phosphorus 32
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
Tc-99m	technetium 99m
μCi	microcurie
SSG	Staff Sergeant
COL	Colonel
CPT	Captain
MAJ	Major
LTC	Lieutenant Colonel
MS	Medical Specialist
MC	Medical Corps
DAC	Department of the Army Civilian