U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-01283/90-001

EA No. 90-035

Docket No. 030-01283

License No. 06-11222-01 Priority 1 Category G1

Licensee: Veterans Administration Medical Center
555 Willard Avenue
Newington, Connecticut 06111

Inspection at: The above address

Inspection conducted: January 31 and February 1, 1990

Inspector: Steven R. Courtemanche 2/15/90
Steven R. Courtemanche, Health Physicist date
Nuclear Materials Safety Section A

Approved by: M. S. Shanbaky 2/15/90
Mohamed M. Shanbaky, Ph.D., Chief date
Nuclear Materials Safety Section A

Inspection Summary: Routine, unannounced inspection conducted on January 31 and February 1, 1990, of the radiation safety program authorized under NRC License No. 06-11222-01. (Report No. 030-01283/90-001)

Areas Inspected: Licensee actions on previous violations, organization and scope of program, internal audits, training and qualification of personnel, radiological protection procedures, use of radioactive materials, storage of radioactive materials, facilities, instruments, receipt and transfer of radioactive materials, radioactive materials waste disposal, transportation of radioactive materials, and independent measurements made by the inspector.

Results: Within the scope of this inspection ten apparent violations were identified: failure to inform the NRC of the Radiation Safety Officer (RSO) leaving the employ of the licensee (Section 3); failure of the Radiation Safety Committee (RSC) to meet at the required quarterly interval and retain records of all RSC meeting minutes (Section 3); failure to perform the annual ALARA radiation safety audit for 1989 and the quarterly review of exposure records for the 4th Quarter of 1989 (Section 4); failure to train radiation workers in the regulations, license conditions, or the use of radiation safety equipment (Section 5); failure to apply the appropriate correction factor for molybdenum-99 when assaying the eluant from a generator (Section 7); failure to perform the dose calibrator linearity test at the required quarterly interval (Section 7); failure to evaluate the result of a dose calibrator linearity test greater than the action level of plus or minus 5 percent (Section 7); failure to perform xenon-133 lung studies in a room kept at a negative pressure relative to surrounding rooms (Section 7); failure to perform required contamination and radiation surveys of spent technetium-99m generators before shipment to the supplier (Section 11); failure to retain records for the decay in storage of Nuclear Medicine Department radioactive wastes (Section 12).

DETAILS

1. Persons Contacted

Albert U. Buatti, M.S., Radiation Safety Officer (RSO)
*Shelby Fine, Acting Medical Center Director
*Edward Kobylanski, Administrative Assistant
*Shutish C. Patel, M.D., Chief of Staff
*Jane Sheedy, Quality Assurance Coordinator
*Mozafaredidin Karimedini, M.D., Visiting Authorized User
*Cornelia Coury-Gerarde, Nuclear Medicine Technologist

*Present at exit interview

2. Licensee Action on Previous Violations

(Closed) 87-001 Licensee did not possess a high range survey instrument as required by the license. The licensee has purchased and possesses a high range survey meter.

3. Organization and Scope of Program

The Veterans Administration Medical Center (VAMC), located in Newington, Connecticut, is authorized to possess and use licensed byproduct material for diagnostic and therapeutic nuclear medicine and research with animals and humans under a Medical Broad Scope License. The research program has been dormant since the last inspection on July 31, 1987. The Nuclear Medicine Department is responsible for all diagnostic and therapeutic procedures. The radiation safety program, at the time of the inspection, was assigned to the nuclear medicine technologist. The licensee stated that the Radiation Safety Officer is no longer an employee of the licensee but can be contacted and would assist in case of emergency. The Radiation Safety Committee is composed of the proper personnel and does discuss matters pertinent to radiation safety.

Failure to inform the Nuclear Regulatory Commission of the departure of the RSO from the employ of the licensee is an apparent violation of Condition 20 of the license as committed to in the license application dated February 28, 1984.

At the time of inspection, no research was being conducted under the VAMC license. All research being performed in Building 5 of the facility was being conducted under the Broad Scope License of the University of Connecticut Health Center (NRC License No. 06-13022-02).

The inspector discussed with the nuclear medicine technologist the scope of the nuclear medicine program. The Nuclear Medicine Department is staffed by one technologist, and an additional nuclear medicine technologist has been hired to begin work in February. This is a decrease from the previous inspection conducted on July 31, 1987 when there were six technologists working in the Nuclear Medicine Department and the Radioimmunoassay Laboratory. The attrition of personnel has been occurring since mid-1988. An average of four to eight diagnostic procedures using radiopharmaceuticals are performed each day and one or two therapy procedures using iodine-131 are performed each year. The licensee receives a 2 Curie technetium-99m generator each week, from which diagnostic kits are constituted. Unit doses for studies not using technetium-99m are received by the licensee from a radiopharmaceutical supplier for the day of use. Lung studies are performed using xenon-133 as single doses. Procedures involving the use of xenon-133 were performed once a month.

The inspector reviewed the organization and assignment of responsibilities of the licensee's radiation safety program. The technologist is on-call for emergency work during the weekend. As stated previously, the RSO is no longer an employee of the licensee. He left the institution in July 1989. If there is an emergency, the technologist can get in touch with the former RSO for help. The technologist now reports to the Chief of Staff, since there are no longer any authorized users in the employ of the licensee. The licensed program has been overseen by visiting authorized physicians since December 1989. Requests for equipment or funds go through the Chief of Staff.

The inspector expressed concern to the licensee's representative about the reduction of the licensee's radiation safety program and the apparent lack of management oversight of licensed activities. The inspector noted that the apparent lack of supervision may have contributed to licensed activities not being conducted in complete compliance with regulatory requirements. The loss of the Chief of Nuclear Medicine, five of six nuclear medicine technologists, including the Chief Technologist, and the RSO appears to have compromised the quality of the radiation protection program, supervision, and oversight of the licensed activities as evidenced by the numerous apparent violations set forth in this report.

The licensee's representative stated that a draft amendment request for a new RSO was being worked on, a new nuclear medicine technologist had been hired but had not started as yet, and training in the regulations, license conditions, and the use of radiation safety equipment would be given.

The Radiation Safety Committee (RSC) is required to meet at a quarterly interval as committed to in the license application dated February 28, 1984. Membership includes the administrator of the hospital, the RSO, a member of the nursing staff, and members from each department where radioactive material is used. Meeting minutes show that pertinent issues are discussed regarding radiation safety. The RSC, however, did not meet during the 4th Quarter of 1989, nor was a record retained of the meeting held during the 3rd Quarter of 1989. Also, the inspector noted that the RSC did not discuss and recommend appropriate action relative to the loss of staff and its impact on program performance.

Failure of the RSC to meet quarterly and to retain a copy of the meeting minutes for the 3rd Quarter of 1989 is an apparent violation of Condition 20 of the license.

The licensee's representative stated that RSC meetings would be conducted quarterly and that the minutes for the 3rd Quarter of 1989 were probably on a computer that had been sent to the University of Connecticut Health Center. Efforts would be made to retrieve the minutes.

4. Licensee Internal Audits

The inspector reviewed the licensee's internal audit program by reviewing records and interviewing personnel. The nuclear medicine technologist stated that the RSO and the chief nuclear medicine technologist were responsible for performing the audits of the program. The former RSO stated that he performed the audits each quarter that he worked for the licensee. The findings of the RSO were reported each quarter to the RSC and were documented in the meeting minutes.

The minutes of the RSC indicated that a quarterly review of the exposure records was performed when the RSC met. There were no occurrences of an exposure requiring investigation by the licensee, which was confirmed by the inspector's examination of the licensee's radiation exposure records. The quarterly review of the exposure records was not performed by the licensee during the 4th Quarter of 1989; this was confirmed verbally by the former RSO. The inspector noted that the RSO is no longer employed by the licensee and that he attended this inspection upon the request of the nuclear medicine technologist.

The last annual ALARA review of the entire program was performed in November of 1988, as documented in the RSC minutes for the 4th Quarter of 1988. The former RSO stated that an ALARA review had not been performed during 1989. The licensee had committed in the license application dated February 28, 1984, to performing the quarterly review of exposure records and an annual review of the ALARA program.

Failure to review occupational radiation exposure records quarterly and perform the annual ALARA review of the program annually is an apparent violation of Condition 20 of the license.

The Chief Nuclear Medicine Technologist (CNMT) left the licensee's employ in October of 1989. The remaining nuclear medicine technologist only had been responsible for the preparation and administration of radiopharmaceuticals to patients before October, 1989. Since that time, she was assigned all duties relating to radiation safety. Since December of 1989, the licensee has used visiting authorized physicians to maintain its licensed program. The use of visiting physicians and a technologist not familiar with the applicable regulations and radiation safety duties appears to have contributed to further deterioration in program performance.

The licensee's representative stated that several corrective actions are in progress or will be taken. These actions include the preparation of a letter to the NRC designating a new RSO, the hiring of a nuclear medicine technologist who was due to begin work late in February, the giving of additional training to the remaining technologist in the regulations, license conditions, and use of radiation safety equipment, and the contracting of two physicians who can be made authorized users for the Nuclear Medicine Department.

No further violations were identified.

5. Training and Qualification of Personnel

The inspector interviewed personnel and examined records to determine the scope of the licensee's training program and the qualifications of personnel involved in radiological safety.

Training in radiation safety for radiation workers and ancillary personnel was the responsibility of the RSO as committed to in the license application dated February 28, 1984. The training was given by the RSO in November of each year, while he was there, and all personnel are encouraged to attend the semi-annnual lectures in radiological health given by the University of Connecticut Health Center.

The nuclear medicine technologist was given training by the CNMT on radiation safety procedures before the CNMT left the licensee's employ. The inspector interviewed and observed the nuclear medicine technologist and reviewed records of surveys performed by the nuclear medicine technologist. Based on the inspector's observations and review, inadequacies in technologist training in radiation safety included the following:

1. Failure to train the technologist in the requirement to perform removable contamination and radiation surveys of spent generators before shipping them back to the supplier (See Section 11),

2. Failure to train the technologist in properly evaluating the molybdenum-99 breakthrough test using manufacturer's instructions (See Section 7),

3. Failure to train the technologist in properly evaluating the wipe samples for the weekly area removable contamination survey (See Section 6).

Failure to provide training in the regulations, license conditions and proper use of radiation safety equipment is an apparent violation of 10 CFR 19.12.

The licensee's representative stated that additional training in the regulations, license conditions, and the use of radiation safety equipment would be given.

6. Radiation Protection Activities

The inspector reviewed the program for radiation protection activities in the Nuclear Medicine Department. Records of personnel exposure were reviewed. No exposures in excess of regulatory limits were noted by the inspector. The maximum recorded quarterly whole body exposure was 130 millirem. The maximum quarterly recorded extremity exposure was 450 millirem. These exposure levels are well below the regulatory limits.

Records of surveys of unrestricted areas, storage areas, and places of use were reviewed. Daily ambient radiation surveys in the Nuclear Medicine Department were made and recorded after each day of use. The weekly area removable contamination surveys had not been performed from July through October of 1989. When the nuclear medicine technologist took over these duties in October 1989, she noted the fact that the weekly removable contamination surveys were not being performed. She immediately started to perform weekly removable contamination surveys, which were assayed using a Ludlum Model No. 177 detector with a GM probe. The technologist did not know what the efficiency for the instrument was and could not demonstrate that the instrument could detect the required detection sensitivity of 200 disintegrations per minute (dpm) per 100 square centimeters. The commitment to perform removable contamination surveys so as to be able to detect 200 dpm per 100 square centimeters is found in the license application dated February 28, 1984 and incorporated into the license by License Condition 20.

Failure to adequately evaluate the results of the weekly area removable contamination survey is an apparent violation of Condition 20 of the license.

The daily ambient and weekly area removable contamination survey results in the Nuclear Medicine Department were recorded as a check mark or an X signifying that levels did not exceed listed background levels. This is acceptable practice under the present license conditions, but the licensee was advised that the regulations in 10 CFR 35 (Revised April 1, 1987) require that all measurements be noted in millirem per hour or in dpm when the current license is renewed. The current license expires November 30, 1990.

The licensee performed surveys after patients received therapeutic quantities of iodine-131 (greater than 30 millicuries). These surveys included one at three feet from the patient, one at the door of the patient's room, one in the main hallway, one in the hallway alongside the patient's room, and one in the laundry room (which is adjacent to the room assigned to patients who receive I-131 therapy). The inspector reviewed records of these surveys. The record of the survey showed the first three measurements, but not the results of the survey made of the laundry room or of the hallway alongside the patient's room. This is acceptable in accordance with the present license conditions; however, the licensee is advised that the regulations in 10 CFR 35 (Revised April 1, 1987) require that, when the current license is renewed, all measurements made to assure compliance with the regulations be recorded.

The inspector reviewed leak test records. The dose calibrator reference sources had been leak tested every six months by the RSO. The licensee did not possess any other sealed sources.

No further violations were identified.

7. Use of Radioactive Materials

The inspector observed the startup procedures for the Nuclear Medicine Department and the use of licensed material. Startup procedures observed included package opening procedures, dose calibrator constancy test, operational check of the radiation detection instrument, and flood tests of the gamma camera. Licensed material was used in accordance with the licensee's procedures or the procedures supplied by the manufacturer.

The inspector reviewed the records of the dose calibrator tests. The constancy test was performed properly on each day of use. The licensee uses a technetium-99m generator and is required to perform the molybdenum-99 breakthrough test on each eluant from the generator. The molybdenum-99 breakthrough test was done on each eluant, but the manufacturer's instructions were not followed. Specifically, the value for the test was recorded as "minimal" rather than in microcuries of molybdenum-99, and the manufacturer's correction factor of 3.5 times the assayed molybdenum-99 value was not used.

Failure to perform the molybdenum-99 breakthrough test in accordance with the manufacturer's instructions is an apparent violation of 10 CFR 35.14(b)(4)(ii). (Reference is to the requirement in the superceded version of 10 CFR Part 35. The same requirement is in the revised 10 CFR Part 35.204).

The dose calibrator linearity test was performed using the Calicheck sleeve method and the manufacturer's instructions over the range of use, as committed to in the license application dated February 28, 1984. The linearity test is required to be performed once each quarter. The linearity test was performed in March, June, and November of 1989 and once in each quarter in 1987 and 1988. The linearity test was not performed during the 3rd calendar quarter of 1989. The RSO performs this test and is required by the manufacturer's instructions to take specified action in accordance with Condition 19 of the license if a result is greater than plus or minus 5 percent from the expected value. In March, 1989, the dose calibrator linearity test result was greater than 5 percent from the expected value and the RSO did not take the specified action. The former RSO, when questioned by the inspector, had thought that all of the results were within the required range. The manufacturer's instructions require that, if any values fall outside the plus or minus 5 percent limit, the study be repeated to rule out possible variations in the initial data.

Failure to perform the dose calibrator linearity test during the 3rd quarter of 1989, and to take action when a result exceeded the action level, is an apparent violation of Condition 19 of the license.

The licensee's representative stated that linearity tests would be conducted quarterly and that the failure to take action when the dose calibrator linearity test result exceeded the action limit was an oversight. No commitment was made as to the method of assuring future compliance.

The inspector interviewed the nuclear medicine technologist regarding the conditions under which xenon-133 lung studies were performed. The technologist stated that, even though the whole department area is kept at negative pressure with respect to the building atmosphere, the room in which the xenon studies are performed is not at negative pressure relative to the rest of the department. This situation had been called to the attention of management by the technologist and had been documented in the RSC minutes beginning in 1986, but remained uncorrected at the time of the inspection.

Failure to administer radioactive gases only in rooms that are at lower pressure than the surrounding rooms is an apparent violation of Condition 20 of the license, as committed to in the license application dated February 28, 1984.

8. Storage of Radioactive Materials

The inspector toured the licensee's facilities and observed the storage of materials. The Nuclear Medicine Department Hot Laboratory has a lock for which only authorized individuals have a key. All licensed materials are kept in the Hot Laboratory, except for off-duty hour deliveries, which are kept in a locked room by Security until Nuclear Medicine Department personnel bring the materials to the Hot Laboratory.

No violations were identified.

9. Facilities

The inspector toured the facilities of the Veterans Administration Medical Center where radioactive material is stored or used. These facilities were located in the Nuclear Medicine Department. The Radioimmunoassay Laboratory has been shut down and there is no research at the facilities covered by the licensee's license. All research in Building 5 is conducted under the Broad Scope License issued to the University of Connecticut Health Center. These activities were not reviewed during this inspection, but were determined to be authorized by the University license. The VAMC facilities were as described in the license application.

No violations were identified.

10. Instruments

The inspector reviewed the instrumentation possessed by the licensee and the records of calibration. The inspector observed that the Nuclear Medicine Department is equipped with two survey meters and an area monitor. The survey instruments, a Ludlum Model 16 equipped with a Geiger-Mueller probe and a Keithley ion chamber, meet the requirements of 10 CFR 35.220. The area monitor is a Ludlum Model 177 equipped with a Geiger-Mueller probe. Calibration records of these instruments were reviewed by the inspector and were found to be in order.

No violations were identified.

11. Receipt and Transfer of Radioactive Materials

The inspector observed the package receipt and opening procedures performed by the technologist in the Nuclear Medicine Department. Radioactive materials receipt and transfer records were also examined.

The inspector determined that the technologist did not perform a radiation survey of spent technetium-99m generators, nor perform a swipe for removable contamination, before shipping the generators back to the supplier.

Failure to perform a radiological survey or perform a swipe for removable contamination of packages containing radioactive material is an apparent violation of 49 CFR 173.475.

12. Radioactive Materials Waste Disposal

The inspector reviewed records of waste disposal and interviewed the technologist in the Nuclear Medicine Department. The records for decay-in-storage for the research program and the Radioimmunoassay Laboratory indicated that the radioactive waste was held for a period greater than 10 half-lives. The radiological release survey results were indistinguishable from background. There were, however, no records for the radioactive waste generated by the Nuclear Medicine Department held for decay-in-storage. When asked by the inspector, the nuclear medicine technologist stated that all radioactive waste held for decay-in-storage was surveyed before discarding the waste in the normal trash and is held for 10 half-lives.

Failure to record the results of the radiological survey required for licensed material held for decay-in-storage is an apparent violation of 10 CFR 20.201(b).

13. Transportation of Radioactive Materials

The inspector examined the licensee's program involving the transportation of licensed material. The technologist stated that spent generators and unused or spent unit doses from the Nuclear Medicine Department are returned to the supplier. Unit doses are returned as limited quantities. The generators are sent back as Radioactive Yellow-II containers (See also Section 11).

No violations were identified.

14. Misadministrations

The inspector examined the licensee's program for reporting misadministrations. No misadministrations have occurred since the last inspection. This was confirmed by an examination of the records and interviews with the RSO and the nuclear medicine technologist.

No violations were identified.

15. Independent Measurements

Radiation levels in the Nuclear Medicine Department were measured by the NRC inspector with an Eberline E-120 Geiger-Mueller survey meter with an end-window probe calibrated with cesium-137. The levels were found to be within the licensee's action levels (i.e., 0.2 mR/hr in unrestricted areas and 2.0 mR/hr in restricted areas).

No violations were identified.

16. Exit Interview

The inspector reviewed his findings with the individuals indicated in Section 1. During the meeting, the inspector described the apparent violations identified and program weaknesses described in this inspection report.