

U.S. NUCLEAR REGULATORY COMMISSION  
REGION I

INSPECTION REPORT

Report No. 030-14526/96-002

Program Code 2110

Docket No. 030-14526

License No. 37-00062-07

Priority 1

Category G1

Licensee: Department of Veterans Administration Medical Center  
University and Woodland Avenues  
Philadelphia, PA

Facility Name: Department of Veterans Administration Medical Center

Inspection At: Department of Veterans Administration Medical Center  
University and Woodland Avenues

Inspection Conducted: October 29, 31 and November 5, 6, 7, 13, 14, 19, and 20, 1996 and April  
15, 16, 21, 22, and 29, and May 13, 1997

Inspectors:

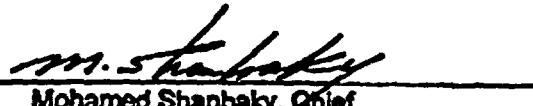
  
David Everhart  
Health Physicist

9/3/97  
date

  
Thomas K. Thompson  
Sr. Health Physicist

9/3/97  
date

Approved By:

  
Mohamed Shanbaky, Chief  
Nuclear Materials Safety Branch 1  
Division of Nuclear Materials Safety

9/4/97  
date

**Inspection Summary:** Special, unannounced safety inspection conducted between October 29, 1996 and May 13, 1997. (Inspection Report No. 030-14526/96-002)

**Areas Inspected:** Organization and Scope of Licensed Activities; Training; Internal Audits and Surveys; Laboratory Inspections; Security of Radioactive Material; Radiation Safety Committee; Radioactive Waste Management Program; Receipt of Radioactive Material; Personnel Radiation Protection; and Control of Radioactive Materials.

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**Results:** Within the scope of this inspection nine (9) apparent violations were identified:

1. Failure to post a Notice of Violation and proposed imposition of civil penalty. (Section 2.A.)
2. Failure to promptly distribute the Radiation Safety Committee (RSC) meeting minutes. (Section 2.B.)
3. Failure to properly sign and maintain the RSC meeting minutes. (Section 2.B.)
4. Failure to take corrective action to repair or replace a dose calibrator which had an error exceeding 10 %. (Section 2.D.)
5. Failure to properly label radioactive waste containers. (Section 2.E.)
6. Failure to include all the required information on waste records. (Section 2.E.)
7. Failure to secure from unauthorized removal or limit access to licensed materials that are stored in controlled or unrestricted areas. (Section 4)
8. Failure to review on the basis of safety and approve or deny intramuscular xenon studies. (Section 2.C.)
9. Failure to measure thyroid burdens within 3 days of administration. (Section 2.F.)

## DETAILS

### 1. Persons Contacted

- \* Earl Falast, CEO
  - \* Margaret O'Shea, Assistant CEO
  - Peggy Jones, Assistant CEO Secretary
  - Claudia Saxton, CEO Secretary
  - \* Philip Hatsis, Chief of Engineering Service
  - Harry Henrich, Assistant Chief of Engineering Services
  - \* Stephen Pahides, Counselor
  - \* Ann Lovell, Radiation Safety Officer
  - \* Gloria Mc Gilman, RSO Counselor
  - Ethel Sessions, Radiation Safety Office Program Assistant
  - \* Martin Zloty, M.D., Chief of Nuclear Medicine Service
  - William David, Chief Nuclear Medicine Technician
  - Adriana Rouch, Nuclear Medicine Technician
  - Jeff Taylor, Nuclear Medicine Technician
  - Cliff Reyes, Nuclear Medicine Technician
  - Linda Albert, Nuclear Medicine Technician
  - Cindy Bennet, Cardiology Technician
  - Sonya Pochas, Nuclear Medicine Secretary
  - \* Francis K. Herbig, Director, National Health Physics Program
  - \* Paul Yurko, Eastern Regional Representative, National Health Physics Program
  - Dr. Thomas Kleyman, Principle Investigator,  
        Chair, Bio-Hazard/Radiation Safety Committee-Research
  - Dr. Wen, Principle Investigator
  - Monica Crane, Research
  - Quiyang Li, Research
  - Ira Yu, Research
  - Xingyao Wu, Research
  - Monica Villar, Research
  - Lisa Antes, Research Fellow
  - John Toremi, Research
  - Jkribettuu Vaman, Research
  - Alan Gabriel, Research
  - Terence McGarvey, Research
- \* signifies attendance at the exit meeting.

### 2. Radiological Safety Program Oversight

Program oversight is provided by the Radiation Safety Officer (RSO) who is supported by a Radiation Safety Office Program Assistant (RSOPA). The inspectors noted that the RSOPA job functions were not performed by any individual other than the RSO for the majority of the time the inspection was in progress. The inspectors noted that it appeared that all duties assigned to the RSOPA position were performed by the RSO in addition to other duties assigned to

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the RSO position. Despite a lack of an individual in the RSOPA position, it appeared to the inspectors, that the RSO was dedicating a special and significant effort in providing program oversight and preventing program deterioration.

The inspector reviewed the quarterly audits performed by the RSO and the RSOPA and documented by the RSO. In the audit reports, the RSO identified deficiencies and apparent violations. The RSO findings were documented in written reports distributed to the director of nuclear medicine and to principle investigators in research. The RSO identified potential safety issues, however, it appears that corrective actions were not always implemented by management. Issues identified in the audits are discussed at the Radiation Safety Committee (RSC) meetings. Additionally, in some cases, the RSO has communicated verbally and via memoranda and E-mail to the facility managers in an attempt to alert them to potential regulatory issues. These actions also have not always resulted in effective actions being taken by facility management. Specific incidences noted by the inspectors are as follows:

- A. The RSO made repeated attempts from January 1996 until October 30, 1996 to inform facility management of the requirements in 10 CFR 19.11 which require the timely posting of Notices of Violation (NOV), proposed imposition of civil penalties and the licensee responses to the NRC on these issues. 10 CFR 19.11(e) requires, in part, that Commission documents posted pursuant to paragraph (a)(4) shall be posted within 2 working days after receipt of the documents from the Commission; the licensee's response, if any, shall be posted within 2 working days after dispatch by the licensee. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later. The licensee management admitted that they did not post the NOV dated January 4, 1996, their reply letters dated February 23, 1996, May 6, 1996, or the NOV and Proposed Imposition of Civil Penalty dated September 18, 1996. The inspectors noted the following from records and interviews with the RSO, Chairman of the RSC and CEO of the facility:
- i) The RSO indicated that she had requested management to provide a copy of the NOV issued January 4, 1996 for the purpose of review and posting. The RSO made her request prior to NRC issuing the NOV because she indicated she had anticipated its receipt. Management did not provide the RSO with a copy of the NOV until late January 1996, which exceeded the timeliness for posting requirement.
  - ii) In a February 20, 1996 RSC meeting, attended by facility management, the RSO discussed the requirement and need to post. This is indicated in the meeting minutes for that date in which the RSO states that NRC mandates that copies be posted for public display.

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- iii) The RSO stated that on March 5, 1996 she went to both the RSC Chairperson and RSC Management representative and repeated her request for a copy of the licensee's reply letter to the January 4, 1996 NOV. The RSO stated that she received a copy on March 6, 1996 which was dated February 23, 1996 which also exceeded the two day timeliness for posting requirement.
- iv) On September 19, 1996 the RSO E-mailed the Chief of Engineering Services, the assistant Chief of Engineering Services and the Chairman of the RSC to inform them of the specific posting requirement and the need to have the September 1996 NOV and Proposed Imposition of Civil Penalty for posting. Management did not provide a copy to the RSO as of October 30, 1996.
- v) The Chairman of the RSC recalls that he received the E-mail message requesting the September NOV and within a few days took the issue directly to the CEO. The Chairman indicated that he and the CEO then talked with the Assistant CEO secretary to get a copy for himself and asked her to take care of distributing a copy to the RSO.
- vi) The Chief of Engineering Services indicated although he read the E-Mail, he knew he did not have a copy so he ignored it. He stated he was out of town the following week and forgot about it.
- vii) The CEO indicated on October 29, and again on October 31, 1996 that he was unaware of any posting requirement and that he did not recall being consulted on this matter. He indicated that the first time he became aware of this was when the inspectors informed him on October 29, 1996.
- viii) The Assistant CEO stated that she discussed the September 1996 NOV with the Director of the Department of Veteran Affairs, National Health Physics Program, soon after receiving it. The Assistant CEO indicated that the Director of the National Health Physics Program did not mention that posting was required.

During interviews with nuclear medicine technologists the inspectors asked if the technologists were aware of the September 1996 proposed civil penalty and NOV. None of the individuals interviewed as of October 31, 1996 were aware of the specific issues. Some technologists were aware that there was an ongoing action by NRC, but no details were known.

The inspectors were concerned that in addition to the failure of the management to assure these documents were posted, that employees in the nuclear medicine department had not been provided sufficient information to make them aware of the issues. The inspectors were concerned that management failed to assure that the employees were aware that harassment, intimidation or discrimination for

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contacting the NRC was not to be tolerated and that management did not assure the staff that it is appropriate to contact the NRC at any time. The inspectors also expressed their concern regarding the apparent lack of communication and cooperation between the RSO and management and informed the licensee that although these undesirable working conditions had not resulted in significant radiological safety problems to date, the continuation of these conditions could potentially lead to radiation safety problems. The failure to post these documents in the required two days for the required duration of 5 working days or until the actions correcting the violation have been completed is an apparent violation of 10 CFR 19.11.

The inspectors believe that this failure is an indication of a lack of effort to assure effective communication and cooperation between management, the RSC, RAM users, and the RSO.

- B. On January 5, 1996, the RSO sent a memorandum to the RSC Chairman requesting a copy of RSC meeting minutes for meetings held May 16, 1995, October 24, 1995, November 17, 1995, November 22, 1995 and December 19, 1995. The Memorandum also specified the regulatory requirement that each member must promptly receive a copy of the meeting minutes which must include the date of the meeting, members present, members absent, summary of deliberations and discussions and recommended actions and the numerical results of all ballots as well as ALARA Program reviews described in 10 CFR 35.20(c). The RSO stated that she was unable to obtain copies of these RSC meeting minutes. The inspectors noted the following from a records review and interviews with the Chairman of the RSC, CEO, and RSO:
- i) The RSC Chairman indicated to the inspectors that he was not familiar with the procedures as submitted to NRC in their license application dated May 5, 1994, with regard to how the meeting minutes were to be officiated. The Chairman indicated that he had not satisfied the RSO's request since he had not prepared the December 19, 1995 meeting minutes as of November 14, 1996.
  - ii) Neither the CEO, Assistant CEO, the Chairman of the RSC, nor the RSO had a complete set of RSC meeting minutes as of November 14, 1996. The CEO was unaware of the location where an official copy of the meeting minutes were kept as of November 14. The licensee's procedures indicate that the location where approved minutes will be maintained will be designated by the Director (CEO).
  - iii) The CEO stated on November 7, 1996 that any set of meeting minutes that were not signed by a member of the CEO's office were not official. None of the meeting minutes as of November 14, 1996 were signed as required by the licensee's procedures. This includes signature blocks for the CEO, Chairman of the RSC and Chief of Staff.

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The licensee's failure to promptly distribute the RSC meeting minutes is an apparent violation of 10 CFR 35.22 (a) (5) and failure to follow procedures in Memorandum No. 00-134 for approval, routing and maintaining the minutes, is an apparent violation of Condition 23 of the license which requires the licensee to conduct their program in accordance with their January 22, 1991 application which includes Medical Center Memorandum No. 00-134 (pg.4).

The inspectors believe that this failure is an indication of a lack of effort to assure effective communication and cooperation between management, the RSC, RAM users, and the RSO.

- C. The inspectors noted that a procedure involving the administration of xenon-133 in a saline solution was being used in nuclear medicine, however, there was no indication that the procedure received the review and approval of the RSC as required by the licensee's procedures.

The failure of the licensee's RSC to meet the administrative requirement of review on the basis of safety and approve or deny all requests for use of radioactive materials, as described in Medical Center Memorandum No. 00-134 as revised March 1994, (pg. 2), is an apparent violation of Condition 23 of their license which requires that they conduct their program in accordance with their January 22, 1991 application which includes Medical Center Memorandum No. 00-134 as revised in March 1994, (pg. 2).

The inspectors believe that this failure is an indication of a lack of effort to assure effective communication and cooperation between management, the RSC, RAM users, and the RSO.

The NRC, in cooperation with the FDA, is continuing to review the xenon-133 procedure to determine if it is an authorized procedure. The inspector informed the licensee that this issue will remain unresolved pending completion of NRC review.

- D. In an audit performed September 12, 1996, the RSO identified the results of two constancy tests of the dose calibrator, performed on two separate days July 9, 1996 and August 7, 1996 that differed from the expected values by 18% and 31%, respectively. The constancy test quality control tolerances are +/- 5%. All other daily constancy tests indicated the dose calibrator was functioning normally. The RSO stated that she informed the Chief Technician immediately upon discovery during the audit and the RSC Chairman was given a written report of these findings dated September 27, 1996. During interviews with the technologists, as of November 13, 1996, one of the two technicians who had recorded the discrepancy was unaware that they had done so or of any discussion concerning such discrepancies. The inspectors noted the following from a records review and interviews with the nuclear medicine technicians, Chairman of the RSC, CEO, and RSO:

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- i) The RSO expressed concern that it did not appear that any action was taken or that the Chief Technician was made aware of the discrepancy when it occurred. The person performing the constancy test would have received an error message and audible beep from the dose manager software used by nuclear medicine. Additionally the error tolerance limits are posted on the dose calibrator and in several other places in the area and the technicians appeared to be aware of the tolerance limits.
- ii) The Chief Technician recalled having talked to one technician identified as having performed one of the daily constancy tests at the time the discrepancy was identified in the audit and brought to his attention.
- iii) The audit findings and the RSO's concern were reported to the Chairman of the RSC, who is also the Chief of the Nuclear Medicine Department, in an audit report dated September 27, 1996.
- iv) The Chairman of the RSC stated that after reviewing the September audit he delegated the corrective actions and response to the Chief Technician to complete.
- v) The Chief Technician provided a staff meeting record with signatures of each nuclear medicine technician. The Chief stated that the meeting was held to provide training on the dose calibrator problem identified in the audit. Of the five signatories only the Chief Technician who provided the document had a clear recollection that the meeting took place and addressed the corrective actions indicated.
- vi) Daily constancy of the dose calibrator is important to assure that patient doses are correctly assayed before administration to the patient. No adequate explanation was ever provided for these large calibrator constancy discrepancies and the failure to resolve the discrepancies before proceeding when an unsatisfactory reading was obtained. One of the two technicians involved indicated they were never informed of the discrepancies by the licensee prior to the inspectors interview in November 1996.
- vii) The Chairman of the RSC and the Chief Technician stated that they believed the reason the technicians do not recall this meeting is because the meeting became a shouting match between two employees.

The Licensee's failure to take corrective action, to repair or replace the dose calibrator when the daily constancy error exceeded 10%, is an apparent violation of 10 CFR 35.50(d). The inspectors were concerned that even after the Chairman of the RSC was informed of these problems by the RSO, the actions taken indicate poor communications and follow-up.

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The inspectors believe that this failure is an indication of a lack of effort to assure effective communication and cooperation between management, the RSC, RAM users, and the RSO.

- E. The RSO provided notification of waste records deficiencies identified in nuclear medicine audits on July 9, 1996, September 27, 1996 and again on March 3, 1997. The deficiencies involved a failure to record the specific isotope disposed of, to include the date of the disposal and to properly label the waste. The inspectors noted deficiencies in waste disposal were continuing as identified in the March 3, 1997 audit by the RSO. This includes the failure to label <sup>89</sup>Sr waste placed in waste storage on February 7, 1997 and Iodine 131 wastes removed from a radiopharmaceutical therapy patient's room on April 12, 1997. The <sup>89</sup>Sr waste was not labeled as of April 21, 1997 when the inspectors asked the Chief Technician to check the waste container which was previously identified by the RSO. Later on April 21 the inspectors checked the container and found a label with the date of October 27, 1996. The Chief Technician was asked if the RSO had previously missed the deficiency in her December 1996 audit and why he had not corrected all the waste record deficiencies when this area has been continually identified in audits. The Chief Technician was interviewed again by the inspectors on April 22, 1997, at which time the Chief Technician opened the waste container and determined that the correct date for the waste was February 7, 1997. The Technician admitted he must have misunderstood a communication from the Chief of Nuclear Medicine Service from where he obtained the October 27, 1996 date. The inspectors confirmed the date of the <sup>89</sup>Sr generation from written directive records which indicated a <sup>89</sup>Sr dose was prepared on February 7, 1997.

The licensee's failure to retain records of byproduct material waste disposal containing all of the required information is an apparent violation of 10 CFR 35.92 (b) and the failure to label the waste is an apparent violation Condition 23 of their license.

The inspectors believe that this failure is an indication of a lack of effort to assure effective communication and cooperation between management, the RSC, RAM users, and the RSO.

- F. The RSO has provided notification of thyroid bioassay deficiencies in three recent quarterly audits dated March 3, 1997, December 3, 1996 and September 27, 1996. Two of these incidents were reviewed by the inspectors and did not appear to be violations of NRC requirements.

The September deficiency involved the RSO having difficulty, during the audit, in finding bioassay data maintained by the nuclear medicine staff. Subsequent to the RSO identifying the deficiency, the Chief Technician provided the missing information.

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The March incident involved a physician who was present in the room during the preparation of an Iodine therapy dose but not actively participating in dose administration. The RSO stated she believed the physician should have received a bioassay, however, the Chief Technician stated that the physician asked the RSO at the time of administration if it was necessary and according to him she replied "it would be a good idea". The Chief Technician stated that this was interpreted by him to mean that it was optional and he chose not to do the assay. The licensee's procedure indicates measurements will be obtained for each individual who helped prepare or administer a therapeutic dosage of Iodine-131. Although the inspectors concluded that no violation could be clearly identified, the RSO may have requested the measurement as a precautionary measure. This event was further indicative of poor communications and cooperation between members of the radiation safety program.

In the audit dated December 3, 1996, the RSO indicated that bioassays were not completed within 72 hours after administration of a therapeutic dosage of Iodine-131 as required by licensee procedures. Specifically, following the administration of 25.2 millicuries of I-131 on October 7, 1996, the Chief Technician, who helped prepare the dose, did not have his bioassay performed until October 11, 1996, an interval greater than 72 hours.

The licensee's failure to have measurements made of thyroid burden within three days after administering the dose is an apparent violation of Condition 23 of their license.

The inspectors believe that this failure is an indication of a lack of effort to assure effective communication and cooperation between management, the RSC, RAM users, and the RSO.

### 3. Training

The RSO provided annual training sessions, however, not all individuals in Nuclear Medicine attended Quality Management Training. The RSO provided notification of this deficiency in audits conducted November 18, 1996 and March 3, 1997. Although the Chairman of the Radiation Safety Committee and the Chief Nuclear Medicine Technician were provided the March 3, 1997 audit results within a few days of the audit as of April 29, 1997 they had not determined who had missed the training to correct this deficiency. The inspectors determined that one of the individuals who did not have documentation of attendance of Quality Management Training within the last year, was the Chief Nuclear Medicine Technician.

The inspectors believe that this failure is an indication of a lack of effort to assure effective communication and cooperation between management, the RSC, RAM users, and the RSO.

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#### 4. Security

The inspectors reviewed the control of access to radioactive materials in the form of prepared and spent syringes, stock solutions, dry and liquid waste and during radioactive research in-progress. The licensee has approximately 15 laboratories and an active Nuclear Medicine service. The inspectors reviewed the security of radioactive materials (ram) by performing announced and unannounced visits to the laboratories on numerous occasions and found that with one exception, all observed ram was secured or under the surveillance of a trained individual. The one exception involved a posted laboratory (Room 314) found unlocked during a "walk-through" of the research facility. This particular laboratory reportedly contained small quantities of radioactive materials, approximately ten microcuries of Sulfur 35's dry radioactive waste. The door was closed, but unlocked and no licensee personnel entered the laboratory except for the RSO, who was accompanying the inspector. The inspector noted that the lights were off in the laboratory and after waiting about 10 minutes, noted that no one entered the lab. Prior to leaving the area, the RSO locked the laboratory. The failure to secure from unauthorized removal or access, licensed material that is in a controlled or unrestricted area is an apparent violation of 10 CFR 20.1801.

The inspectors noted the facility is in the process of completing installation of a card key access system for the research laboratory area to control access. The system was installed as of April 29, 1997, however, the training had not been completed to assure personnel do not permit others to enter when using their cards. The licensee indicated the full implementation of the system will occur within a few months.

#### 5. Exit Meeting

An exit meeting was held on May 13, 1997, with those individuals noted in Section I. During the exit interview, the inspectors presented the inspection findings and Region I management expressed their significant concern about the lack of communication and cooperation among the licensee's management, the RSC, RAM users, and the RSO.