U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 030-02623/89-001
030-11781/89-001
070-03042/89-001

Docket Nos. 030-~~03016~~ 02623 D.C.
030-11781
070-03042

License Nos. 31-02892-01 Priority 1 Category G1 Program Code 02110
31-02892-05 1 G3 02300
SNM-1969 7 K 22160

Licensee: V.A. Medical Center
800 Poly Place
Brooklyn, New York 15224

Inspection Conducted: July 13 - August 21, 1989

Inspector: _____ 22 September, 1989
John M. Pelchat, Health Physicist date
Nuclear Materials Safety Section A

Approved by: _____ 9/26/1989
Mohamed M. Shanbaky, Ph.D., Chief date
Nuclear Materials Safety Section A

Inspection Summary: Routine, Unannounced Safety Inspection conducted July 13 - August 21, 1989 (Combined Inspection Report 030-02623/89-001, 030-11781/89-001, 070-03042/89-001)

Areas Inspected: Corrective Actions on Previously Identified Violations; Program Scope and Licensee Organization; Radiation Safety Training; Personnel Radiation Protection; Radioactive Material Handling Procedures; Radioactive Waste Disposal; Teletherapy Program; and Nuclear Cardiac Pacemaker Program.

Results: Within the scope of this inspection, 14 apparent violations were identified: failure to amend radioactive material license to add new radiation safety officer (RSO) (Section 3); failure to assign oversight responsibility to RSO or other qualified individual (Section 3); failure to appoint representatives from teletherapy and pacemaker departments to radiation safety committee (Section 3); failure to provide radiation safety training (Section 4); failure to adequately evaluate whole body radiation exposures (Section 5); failure to require individuals handling radioactive materials to wear lab coats and radiation dosimetry (Section 5); failure to adequately evaluate incoming radioactive material package contamination wipe samples; (Section 6); failure to perform direct radiation survey measurements of radiopharmaceutical elution, preparation, and injection areas on a daily basis (Section 6); failure to adequately evaluate weekly nuclear medicine area radioactive contamination wipe samples (Section 6); failure to adequately evaluate sealed source leak tests (Section 6); failure to check teletherapy room area radiation monitor on each day of use (Section 8.2); failure to maintain teletherapy system monthly spot check records containing all required information (Section 8.2); failure to maintain teletherapy system annual full calibration records containing all required information (Section 8.2); and failure to perform required five year service of teletherapy source assembly (Section 8.2).

8910200186 890927
REG1 LIC30
31-02892-01 PDC

DETAILS

1. PERSONS CONTACTED

*James J. Farsetta, Director
*C. Jae Kim-Nam, M.D., Acting Chief, Radiology
*Albert Debons, Ph.D., Radiation Safety Officer
Angelo Porcari, M.D., Senior Nuclear Medicine Resident Physician
Hollis Ross, Supervising Nuclear Medicine Technologist
Frank Dawry, Nuclear Medicine Technologist
Ludwig Bierman, Chemist, Radioimmunoassay Laboratory
Gabe Solomon, Ph.D., Research Investigator
Dennis Kinney, Ph.D., Research Investigator
Bijoyish Mookerjee, M.D., Research Investigator
Luckner Vivien, Teletherapy Technician
Geraldine Jones, Teletherapy Technician
Joseph Yanish, Administrative Officer, Radiology Service
*Kathy Gaine, R.N., Program Coordinator
John Fountaine, M.D., Cardiac Pacemaker Clinic
Carmen Perri, R.N., Cardiac Pacemaker Clinic
*Arthur Trappier, Consulting Teletherapy Physicist

* - denotes persons present at exit conference

2. CORRECTIVE ACTIONS ON PREVIOUSLY IDENTIFIED VIOLATIONS

(Closed) Inspection 87-001: Failure to perform necessary surveys to assure compliance with the radiation exposure standards established in 10 CFR 20. Specifically, the licensee was cited for failure to monitor extremity radiation exposures and failure to monitor airborne concentrations of radioactive material in restricted areas. In a letter dated May 10, 1988, the licensee stated that the Radiation Safety Officer would oversee Nuclear Medicine Service personnel use of extremity dosimetry. The licensee also stated that breathing zone air monitoring equipment had been purchased and would be utilized. The inspector observed extremity radiation monitoring devices being worn by all persons handling appropriate quantities and types of radioactive material. The inspector also reviewed the results of air monitoring that the licensee was performing during radioactive iodine handling procedures.

(Closed) Inspection 87-001: Failure to maintain decay-in-storage survey results. In the letter dated May 10, 1988, the licensee stated that the Radiation Safety Officer would oversee all radioactive waste decay-in-storage activities including the performance of necessary surveys. Review of waste disposal records indicated that necessary survey records were maintained.

(Open) Inspection 87-001: Failure to maintain adequate records of teletherapy system annual full calibrations and monthly spot checks. In the letter dated May 10, 1988, the licensee stated that the records were maintained as required. However at the time of the inspection not all records were readily available. During the course of the inspection, available licensee personnel located some teletherapy system evaluation records. Additional records were received by mail in the NRC Region I office on August 12, 1989. Monthly spot check records did not include the difference between the anticipated and the measured output of the teletherapy system. Annual teletherapy system full calibration records failed to include the information described in Section 8.2 of this report.

3. PROGRAM SCOPE AND LICENSEE ORGANIZATION

The Veterans Administration Medical Center, located in Brooklyn, New York is authorized to possess and use licensed byproduct material for diagnostic and therapeutic nuclear medicine, teletherapy, and in vitro research. The licensee is also authorized to possess and use 210 milligrams of plutonium-238 for implantation as a component of nuclear powered cardiac pacemakers.

The nuclear medicine service performed an average of 20 diagnostic procedures per day. The teletherapy program treated an average of 26 - 30 patients per day. The licensee had 6 active principal investigators performing research activities involving the use of licensed radioactive material.

Nuclear medicine and research work involving the use of licensed radioactive material were under the supervision of the Nuclear Medicine Service. The monitoring of radiation safety activities in these areas on a daily basis was performed by the Radiation Safety Officer (RSO). The RSO was also responsible for performing dose calibrator constancy tests and limited daily area radiation surveys in the nuclear medicine area. The RSO performed periodic radiation safety audits of research activities. The results of the audits were reported to the Radiation Safety Committee. The RSO was also responsible for the review of all radiation dosimetry records in the facility. The RSO stated that he served in this capacity since early 1988 following the sudden death of the previous RSO. However, none of the radioactive material licenses issued to the facility had been amended to add the new RSO. 10 CFR 35.13(c) requires that a licensee apply for and receive a license amendment prior to changing RSO.

Failure to apply for a license amendment to name a new RSO is an apparent violation of 10 CFR 35.13(c).

The RSO reported to the chief of the Nuclear Medicine Service. The RSO stated that he had no radiation safety oversight of the teletherapy program or the nuclear cardiac pacemaker program. The RSO also stated that he had been instructed by his management that he was not to provide any radiation safety oversight to the teletherapy program other than review of the teletherapy program's dosimetry records. The RSO added that he was not aware of the existence of the licensee's nuclear cardiac pacemaker program until the beginning of the inspection. Review of the licensee's teletherapy license application named the former RSO as being responsible for teletherapy radiation safety. 10 CFR 35.21(a) requires that a licensee appoint a Radiation Safety Officer responsible for implementing the radiation safety program. 10 CFR 35.21(a) further requires that the licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operations of the licensee's radioactive material use program.

Failure of assign radiation safety oversight responsibility for the teletherapy program to the current RSO or another qualified individual is an apparent violation of 10 CFR 35.21(a).

The chief of the Nuclear Medicine Service served as the Chairman of the Radiation Safety Committee. The membership of the Radiation Safety Committee included a staff member from the nuclear medicine and research services, a registered nurse, and a member of the medical center's administration. There were no representatives from the teletherapy staff or the cardiology staff on the Radiation Safety Committee. 10 CFR 35.22(a)(1) requires, in part, that the Radiation Safety Committee membership include an authorized user of each type of radioactive material use permitted under the radioactive material license.

Failure to have an authorized user from the teletherapy and nuclear cardiac pacemaker programs is an apparent violation of 10 CFR 35.22(a)(1).

Review of the Radiation Safety Committee minutes indicated that the committee met at the required quarterly frequency. The Committee meetings included reviews of routine radiation safety business such as ALARA reports, review of new radioactive material use authorization applications, research laboratory audit results, low-level radioactive waste disposal alternatives and corrective actions taken as the result of RSO audits and NRC inspections.

No other violations were identified.

4. RADIATION SAFETY TRAINING

The RSO stated that he provided the nuclear medicine service and nursing service staffs with radiation safety training upon initial employment and during periodic staff meetings. The RSO stated that he also provided radiation safety training to research staff working with radioactive material upon initial employment. The RSO added that supplemental training was provided to research workers on an informal basis during periodic radiation safety audits performed in the research areas.

Several individuals working in research areas where radioactive materials were used and stored were interviewed by the inspector during the course of the inspection. In an area used for research by Dr. Rothenberg, the inspector interviewed two research workers. These individuals had handled radioactive material for one week and had not received any radiation safety training prior to entering a restricted area. 10 CFR 19.12 requires that licensees instruct all persons working in or frequenting any portion of a restricted area in radiation protection, in the procedures and precautions to minimize exposure to radioactive material, the purpose and function of protective devices, and in the applicable provisions of the NRC license and regulations.

Failure to instruct individuals working in restricted areas in radiation protection and in the applicable provisions of the NRC license and regulations is an apparent violation of 10 CFR 19.12.

5. PERSONNEL RADIATION PROTECTION

The licensee issued dosimetry to about 35 persons who were routinely involved in nuclear medicine, teletherapy, and research activities using radioactive material. Film badge dosimeters issued to the nuclear medicine and teletherapy staff were exchanged every two weeks. Dosimetry issued to research workers was exchanged every month. The RSO was responsible for reviewing dosimetry results for all licensee activities involving the use of ionizing radiation, including X-ray and radioactive material. The inspector reviewed radiation dosimetry records for the period beginning November 1987 through June 1989. The maximum recorded quarterly whole body radiation exposure was 140 millirem (mRem). The maximum recorded quarterly extremity radiation exposure was 1000 mRem.

Review of teletherapy radiation dosimetry records indicated that dosimetry issued to a teletherapy physician was returned too late for processing in seven of twelve months during 1988. Dosimetry results for this individual were also not available for an additional month in 1988 as the result of damage to the dosimeter. The licensee performed no evaluation of this person's radiation exposure for the eight months in 1988 for which dosimetry results were missing.

10 CFR 20.201(b) requires that a licensee make adequate surveys to assure compliance with all the requirements of 10 CFR 20. 10 CFR 20.201(a) defines "survey" as an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of circumstances. When appropriate, such an evaluation includes a physical survey of the location of materials and equipment, and measurements of radiation levels or radioactive material concentrations present. 10 CFR 20.101(a) establishes the maximum permissible radiation exposures for radiation workers in restricted areas.

Failure to evaluate radiation exposures of persons working in restricted areas to assure compliance with the requirements of 10 CFR 20.101(a) is an apparent violation of 10 CFR 20.201(b).

During a tour of research areas, the inspector observed two research workers handling radioactive material. In addition to not having received radiation safety training (see Section 4), neither individual was wearing radiation dosimetry or lab coats. The RSO stated that the individuals had just begun working with radioactive material and that their requests for dosimetry was still being processed. In discussing the failure of the two research workers to wear laboratory coats, the RSO stated that the two workers were involved in research that was funded by the National Institutes of Health. The RSO added that a Veterans Administration (V.A.) policy prevented the issue of laboratory supplies, including laboratory coats, for research activities not directly funded by the V.A. The inspector stated that regardless of funding considerations, the V.A. was responsible for assuring that all activities authorized by the NRC licenses were conducted safely and in complete compliance with NRC license and regulatory requirements. License Condition 16 requires that the licensee possess and use licensed radioactive material in accordance with the statements, representations, and procedures contained in the radioactive material license application and in the documents submitted in support of that application. Item 15 of the radioactive material license application dated June 20, 1985 states that radioactive materials will be handled in accordance with the general rules for the safe use of radioactive material described in Appendix G of Regulatory Guide 10.8 (Revision 1), "Guide for the Preparation of Applications for Medical Programs". Item 1 of Appendix G requires that all personnel wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used. Item 7 of Appendix G requires in part, that all personnel wear radiation monitoring devices at all times while in areas where radioactive materials are used or stored.

Failure to wear protective clothing and radiation dosimetry at all times in areas where radioactive materials are used or stored is an apparent violation of License Condition 16.

All other licensee personnel involved in licensed activities were observed to be wearing appropriate protective clothing and radiation dosimetry.

The RSO stated that he monitored all research iodination activities. The RSO stated that breathing zone air samples were collected when iodinations and other activities involving volatile forms of radioactive iodine were performed. The sample collection pumps were calibrated annually and the sample counting system was calibrated before each use. Sample results were evaluated to ensure airborne concentrations of radioactive material were below the maximum permissible concentrations established in Appendix B of 10 CFR 20.

6. RADIOACTIVE MATERIAL HANDLING PROCEDURES

The inspector observed that areas in which radioactive materials were stored and used were properly posted and adequately secured to prevent the unauthorized use or removal of licensed radioactive material.

All radioactive materials, including research materials, were ordered by and delivered to the nuclear medicine service. All radioactive material packages were opened by the RSO or his designee. The inspector observed that appropriate radiation safety precautions were observed and all required surveys were performed. A review of radioactive material package receipt survey records indicated that the results of radioactive contamination surveys, collected when the RSO was absent, were not converted from counts per minute to disintegrations per minute per 100 square centimeters (dpm/100 cm^2). In addition, the results were not evaluated against the licensee's radioactive material package contamination action limit. Item 14 of the radioactive material application states that radioactive material packages will be surveyed and opened in accordance with the procedures described in Appendix F of Regulatory Guide 10.8 (Revision 1). Item 2.f of Appendix F requires the collection and evaluation of radioactive material package contamination samples. Item 1 of Appendix F establishes a radioactive material package contamination action limit of 22,000 dpm/100 cm^2.

Failure to evaluate radioactive material package contamination samples on those days when the Radiation Safety Officer was absent is an apparent violation of License Condition 16.

The RSO was observed performing the required daily dose calibrator constancy test before the instrument was used to assay technetium-99m (Tc-99m) elutions or prepared radiopharmaceuticals. The results of dose calibrator constancy tests were adequately evaluated and recorded. Review of dose calibrator quarterly linearity tests and annual accuracy tests results indicated that these tests were performed and recorded as required.

The licensee procured one 2.5 curie molybdenum-99/technetium-99m generator each week. Review of generator elution records indicated that molybdenum-99 (Mo-99) "breakthrough" was tested and evaluated for each elution as required. Nuclear medicine service staff observed appropriate radiation safety precautions when eluting the generator. Prepared radiopharmaceuticals were contained in labeled vial shields as required.

The inspector observed several administrations of radioactive material to patients. In each case, the nuclear medicine technologist identified the patient by checking their identification bracelet and by calling the patient by his first and last name. Syringe shields were used for each administration. Injections were routinely performed in a chair located in the hot lab. Some radiopharmaceutical injections for "flow" studies were done on patient scanning tables or on a cardiac exercise treadmill.

The RSO stated that he performed daily surveys of the waste baskets throughout the nuclear medicine area to assure that no radioactive material was inadvertently disposed of with non-radioactive trash. However, no other areas including radiopharmaceutical elution, preparation and injection locations in the nuclear medicine area were surveyed on a daily basis. Review of daily radiation survey records also indicated that direct radiation surveys were not performed on weekends during which radiopharmaceuticals were prepared and used. Item 17 of the radioactive material license application states that area radiation surveys will be performed in accordance with the procedures described in Appendix I of Regulatory Guide 10.8 (Revision 1). Item 1 of Appendix I requires that all elution, preparation, and injection areas be surveyed daily with an appropriately low-range radiation survey meter.

Failure to perform daily radiation surveys of all elution, preparation, and injection areas is an apparent violation of License Condition 16.

Item 6 of Appendix I, Regulatory Guide 10.8 states that areas will be decontaminated if weekly radioactive contamination surveys detect contamination in excess of 200 dpm/100 cm^2. However, review of weekly nuclear medicine area contamination survey records indicated that radioactive contamination wipe samples, collected during periods when the RSO was absent, were not converted from counts per minute to disintegrations per minute per 100 square centimeters (dpm/100 cm^2). In addition, the results were not compared to the licensee's area radioactive contamination action limit.

Failure to evaluate radioactive contamination samples to ensure that appropriate action is taken when sample activity exceeds the 200 dpm/100 cm^2 action limit, is an apparent violation of License Condition 16.

Review of sealed source leak test records indicated that leak test results were recorded in counts per minute. The RSO stated that the results were not evaluated against the 0.005 microcurie (uCi) action limit nor was he aware that such a limit had been established. 10 CFR 35.59(b)(2) requires that a licensee test sealed sources for leakage at intervals not to exceed six months. 10 CFR 35.59(c) requires that sealed source leak test samples be evaluated in such a fashion as to be able to detect 0.005 uCi on the sample. 10 CFR 35.59(e) establishes 0.005 uCi as the sealed source leak test action limit at which the licensee should complete certain specific corrective actions.

Failure to evaluate the results of sealed source leak tests against the 0.005 uCi action limit is an apparent violation of 10 CFR 35.59.

7. RADIOACTIVE WASTE DISPOSAL

A review of radioactive waste disposal records indicated that all short-lived radioactive waste is disposed of by decay-in-storage. Decay-in-storage waste disposal records include the waste generation dates, disposal date, radiation survey results. Spent Mo-99/Tc-99m generators were held for about 1 - 2 weeks and were then packaged and returned to the manufacturer. Radioactive waste disposal procedures in the research laboratories were performed in accordance with the requirements established in the license and 10 CFR 20.301 - 20.311. Laboratory personnel were found to be knowledgeable of licensee radioactive waste disposal procedures.

No violations were identified.

8. TELETHERAPY PROGRAM

The AECL Theratron 80 teletherapy unit was located in the radiation therapy office suite. Teletherapy activities were administratively assigned to the Radiology Service. The teletherapy staff was comprised of two teletherapy physicians, two teletherapy technologists, and a secretary. In addition, a consulting teletherapy physicist (referred to hereafter as the "consultant") visited the program one day per week. The consultant reviewed treatment plans and performed required monthly and annual evaluations of the teletherapy system.

8.1 TELETHERAPY SYSTEM TIMER FAILURE INCIDENT

During a review of the RSO's incident file, the inspector found a series of memoranda which indicated that on October 25, 1988, the teletherapy unit timer continued to operate beyond the preset time resulting in the teletherapy source assembly not being returned to the shielded position at the end of the prescribed treatment time while a patient was undergoing treatment. The teletherapy technologist did not manually terminate the treatment or to remove the patient from the radiation beam. Instead, the technologist notified the consultant. The consultant, upon observing the timer malfunction, terminated the treatment manually by depressing a wall mounted button to open the treatment room's pneumatically powered door. This resulted in the immediate return of the source assembly to the shielded position.

The technologist told the inspector that he routinely watched the control panel timer display during the last few moments of a treatment to ensure the unit shut down at the end of the prescribed treatment. The technologist confirmed that when he saw the timer continue beyond the prescribed time, he took no action to manually terminate the treatment or to remove the patient from the beam. The technologist stated that he went to an office which is located approximately 20 - 25 feet away from the control panel and told the consultant to "come see this". The technologist stated that the reason he did not take any action to shut the teletherapy unit down was that he wanted to demonstrate to the consultant that the timer had malfunctioned. The technologist added that both he and the other technologist had reported various system malfunctions to the consultant in the past and the consultant had apparently not believed them when he could not reproduce the problem. Both staff technologists stated that they had repeatedly observed the mechanical timer display on the control panel seemingly continue for 2 - 3 seconds beyond the preset exposure time. The technologists added the problem was very intermittent and did not recur in the presence of the consultant. Both technologists stated that they felt the consultant did not believe them when they reported difficulties with the teletherapy system.

The inspector reviewed the patient's therapy prescription and treatment records. Licensee personnel estimated that the patient's actual treatment duration on October 25, 1988 was 30 seconds longer than the prescribed duration which resulted in the patient receiving 50 additional rads of exposure. The patient's treatment on October 26, 1988 was reduced 30 seconds to compensate for the additional exposure that had been received the previous day. The patient's total radiation dose did not exceed the prescribed radiation dose.

The teletherapy technologist stated that the licensee continued to use the teletherapy unit after the timer malfunction. The technologist also stated stated that he closely watched the timer display in the event the timer malfunction recurred. The teletherapy system timer did not malfunction again. Review of the teletherapy unit mainterance records indicated that the unit's LF 42 mechanical timer was replaced and tested on November 5, 1988, approximately two weeks after the incident.

Interviews with the technologists indicated that neither their supervisors nor the consultant reviewed the timer malfunction or emergency procedures with them after the incident. The teletherapy technologist involved with this incident, stated that he had received prior training in the licensee's emergency procedures. The technologist demonstrated to the inspector that he was familiar with the various methods available for manually shutting down the teletherapy unit.

The technologists also pointed out a label the consultant affixed to the teletherapy system control panel which stated:

881107
Timer Error Correction
0.034 min.

The teletherapy technologists stated that they had not received any information on what the label meant or instructions on how the information was to be used.

One of the technologists stated that the consultant was unresponsive to requests for training. The technologist added that the technologist and the consultant had disagreed on numerous occasions and, as a result, avoided any verbal communication.

The consultant confirmed that communication difficulties existed between him and the teletherapy technologists. The consultant also confirmed that one technologist avoided any conversation with him. The consultant stated that he had tried to provide various therapy texts to the technologists in response to their questions but the technologists had rejected the texts.

The inspector concluded that communications between the consultant and the teletherapy technologists were poor. The incident in which the teletherapy technologist allowed the patient to remain in the beam after the timer malfunctioned in order to demonstrate the malfunction to the consultant was an example of the result of this communication problem. The potential existed for the patient to have received a therapeutic dose of radiation in excess of the prescribed therapy dosage.

8.2 TELETHERAPY SYSTEM SURVEILLANCE PROGRAM

Interview of the two teletherapy technologists indicated that they did not perform any operational test of the teletherapy system treatment room area radiation monitor prior to the system's first use each day nor were they knowledgeable of the requirement to do so. 10 CFR 35.615(d)(3) requires that the teletherapy room area radiation monitor be checked with a dedicated check source for proper operation each day before the teletherapy system is used for the treatment of patients.

Failure to test the teletherapy room area radiation monitor for proper operation with a dedicated check source each day of use is an apparent violation of 10 CFR 35.615(d)(3).

The inspector asked to review monthly spot check and annual calibration records for the teletherapy system. Neither the consultant nor the teletherapy physicians were available at the time of the inspection to assist in the retrieval of records. Review of the monthly spot checks records revealed that the results of these checks were available for the period of September 1987 through August 1988. These records did not include the following information required to be maintained as part of monthly spot check records by 10 CFR 35.634(f):

a. Make, model, and serial number of the teletherapy unit and the sealed source;

b. Make, model, and serial number of the dosimetry system used to make output measurements;

c. The teletherapy system's calculated on - off error;

d. The difference between the anticipated output and the measured output;

e. Assessment of the coincidence of the radiation field versus the light field indicated by the teletherapy unit collimator; and,

f. The operability of the patient viewing system.

The consultant arrived at the facility during the exit conference. The consultant stated that the results of his monthly spot checks as well as annual full calibration measurements were maintained at the facility but the licensee personnel available during inspection were not familiar with their location. The inspector requested that the consultant send copies of these records to the NRC Region I office for review. On August 12, 1989, the licensee provided the additional monthly spot check records. The records provided on August 12 included all of the above required checks except an evaluation of the measured output against the teletherapy system's anticipated output as required by 10 CFR 35.634(f).

Failure to maintain records of monthly teletherapy system spot checks which include all the required information is an apparent violation of 10 CFR 35.634(f). This finding is a repeat violation which was previously documented during the December 15 and 18, 1987 inspection.

The results of the annual full calibration performed in September 1987 were available at the time of the inspection. The record did not include the following information required by 10 CFR 35.632(g):

a. Make, model, and serial number of the teletherapy unit and the sealed source;

b. Make, model, and serial number of the dosimetry system used to make output measurements;

c. Assessment of timer constancy and and linearity;

d. The teletherapy system's calculated on - off error;

e. Accuracy determination of each distance measuring and localization device; and,

f. Assessment of the coincidence of the radiation field versus the light field indicated by the teletherapy unit collimator.

On August 12, 1989, the licensee submitted records of the May 1988 and March 1989 annual full calibration measurements. These records also did not record the above-listed information. No new information was provided concerning the September 1987 full calibration.

Failure to maintain records of annual teletherapy system full calibration measurement results which include all the required information is an apparent violation of 10 CFR 35.632(g). This finding is a repeat violation which was previously documented during the December 15 and 18, 1987 inspection.

Review of records indicated that the teletherapy unit last underwent a source replacement on September 8, 1982. The consultant and the administrative officer responsible for the Radiology Service stated that, to the best of their knowledge, no major service had been performed on the teletherapy unit's source assembly since the source's installation. 10 CFR 35.647(a) requires that licensees shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement, or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

Failure to have the teletherapy unit fully inspected and serviced on or prior to September 8, 1987 is an apparent violation of 10 CFR 35.647(a).

The inspector concluded that the licensee's apparent failure to assign responsibility for the teletherapy program resulted in the deficiencies in the teletherapy system surveillances. Specifically, neither the RSO nor another member of the licensee staff was responsible for assuring that the teletherapy radiation safety program was conducted in compliance with the NRC's regulations. This apparent violation of 10 CFR 35.21(a) is also discussed in section 3 of this report.

9. NUCLEAR CARDIAC PACEMAKER PROGRAM

The licensee is authorized under NRC Special Nuclear Material License SNM-1969 to possess and use 210 milligrams of plutonium-238 for implantation as a component of a nuclear powered cardiac pacemaker. The licensee originally implanted six of these devices between 1973 and 1975. All but one of these devices was subsequently explanted. The single remaining device was implanted on October 11, 1973. The patient was last seen on April 9, 1986 and is no longer clinically followed by the licensee. Clinical patient follow up is now being done at a V.A. Hospital not licensed for the possession or use of nuclear cardiac pacemakers. However, the patient's pacemaker is tracked by the Veterans Administration Eastern Pacemaker Center located in Washington, D.C. The licensee receives copies of the results of the follow ups and records are maintained in the patient's file.

One of the physicians named in the original pacemaker license application still worked in the licensee's cardiac pacemaker clinic. Interviews of the physician and the nurse who maintained pacemaker performance records indicated that they were not familiar with the required pacemaker tracking and recovery regulatory requirements. Also, the RSO was not aware that the licensee possessed a pacemaker license nor was he familiar with the following license requirements:

a. that the NRC be notified of the patient's death, any adverse reaction, or device malfunction within 24 hours of the occurrence of such an incident;

b. that the NRC be notified within 10 days of loss of contact with a nuclear pacemaker patient; and

c. that follow up and replacement of the nuclear pacemaker be performed in accordance with appropriate procedures and that the device be explanted and returned to the manufacturer in accordance with recovery procedures upon the death of the patient.

No violations of NRC regulations or license conditions were identified during this inspection. However, the inspector determined that the lack of management oversight of the nuclear cardiac pacemaker program by the RSO or another qualified individual knowledgeable in NRC requirements, may contribute to future violations if not corrected by licensee management.

10. EXIT CONFERENCE

The inspector summarized the inspection findings, including the apparent violations with the individuals indicated in Section 1. The NRC's enforcement policy was reviewed with the licensee's representatives.