U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Reports No. 030-02271/93001(DRSS)
030-31205/93001(DRSS)
030-15101/93001(DRSS)
030-33008/93001(DRSS)

Dockets No. 030-02271
030-31205
030-15101
030-33008

Licenses No. 24-00167-11
24-00063-13
24-00063-10
24-00167-13

Licensee: Washington University Medical School
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Nuclear Materials Inspection
Section 2

Inspection Summary

Inspection from November 15, 1993 to November 18, 1993 (Reports No. 030-02271/93001(DRSS), 030-31205/93001(DRSS), 030-15101/93001(DRSS) and 030-33008/93001(DRSS)
Areas Inspected: Unannounced, routine inspection of activities conducted under the licensee's broadscope medical license, two self shielded irradiator licenses, and a teletherapy license as they pertain to radiation safety and to

compliance with the Commission's rules and regulations and with the conditions of the licenses. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel. In addition, the inspection focused on five reported incidents which have occurred since the previous inspection conducted November 1992 and one other incident which occurred July 24, 1992, which had not been reported to the NRC.

Results: Of the areas inspected, five apparent violations were identified regarding NRC License No. 24-00167-11 (broadscope): (1) failure to conduct daily end-of-day surveys in radiopharmaceutical preparation areas; (2) failure to perform weekly radiation and contamination surveys in radiopharmaceutical preparation and waste storage areas; (3) failure to discontinue remote afterloader brachytherapy treatment of a patient when patient viewing was not available; (4) unauthorized opening of a sealed source; and (5) failure to control the brachytherapy treatment restricted area as required by license condition.

In addition an apparent violation was identified regarding NRC License No. 24-00063-10 (teletherapy): failure to test the operation of the electrically operated door with the power to the teletherapy unit off.

Five areas of concern were also identified regarding License No. 24-00167-11 (broadscope) during the inspection: (1) inadequate job specific training regarding proper response to emergency situations; (2) failure to properly instruct the nursing staff regarding the need to use the video monitors to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational malfunction of the afterloading device; (3) inadequate job specific training for a technician responsible for the routine leak tests of sealed sources; (4) inappropriate emergency action taken to prevent spread of radioactivity following rupture of a sealed source; and (5) inadequate procedures followed in the performance of area surveys and weekly contamination tests.

Two areas of concern were identified regarding License No. 24-00063-10 (teletherapy): (1) teletherapy physicists and oncologists are not included in the annual teletherapy emergency drills and do not receive specific instructions on this institution's policies and procedures regarding stuck teletherapy sources; and (2) the teletherapy treatment room door is difficult to open with the power to the door turned off.

DETAILS

1. Persons Contacted

*Barry Siegel, M.D., Acting Chair, Radiation Safety Committee (RSC)
*Keith Fischer, M.D., Chief of Nuclear Medicine Service at Jewish Hospital and Member to RSC
*Kathy Hanold, R.N., Director of Women and Infant Services and Nursing Representative to RSC
*H.S. Leahey, Director Industrial Contracts and Licensing and Management Representative to RSC
*Eric Klein, M.S., Radiation Oncology Center Physicist for Jewish Hospital
*Ali Meigooni, Ph.D., Brachytherapy Physicist
*Jackie Fries, R.N., Head Nurse, Barns Hospital
*Susan Baker, Manager, Radiation Oncology
*Walter Davi , Director of Facilities Management and Management Representative to RSC
*Sally Schwarz, M.S., Supervisor of Nuclear Medicine Radiopharmacy, Barnes Hospital
*John Eichling, Ph.D., Radiation Safety Officer (RSO)
*Jeanette Hardin, Assistant RSO
*Dan Szatkowski, Assistant RSO
*Kelly Gushleff, Radiation Safety
*Kevin Ferguson, Radiation Safety
*Bonnie Kelly, Radiation Safety
*Perry Grigsby, M.D., Clinical Chief, Barnes Hospital Radiation Oncology
Jeffery Williamson, Ph.D., Chief Brachytherapy Physicist
Marilyn Johnson, R.N., Nurse, Barnes Hospital

*Indicates those persons in attendance at the exit interview on November 18, 1993.

2. Purpose of Inspection

This was an unannounced routine inspection to examine activities conducted under each of the four licenses as they pertain to radiation safety and to compliance with the Commissions rules and regulations and with the conditions of the licenses. The inspection consisted of selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel. The inspection was performed at the licensee's facilities located at Washington University, Washington University Medical Center, Barnes Hospital, Children's Hospital, Jewish Hospital, and Mallinckrodt Institute of Radiology, all located in St. Louis, Missouri.

3. Licensed Program

Washington University under its broadscope medical license No. 24-00167-11, is authorized to use any byproduct identified in 10 CFR 35.100 through 500 for medical use and any byproduct, source, and/or special nuclear material with atomic numbers 3-83 inclusive for research and development, medical research, diagnosis, and therapy. The University is also authorized to use a variety of other materials for research and development, medical research, diagnosis, and therapy. Special sealed sources used in Low Dose Rate, Pulsed Dose Rate, and High Dose Rate Afterloaders are also authorized by the license for intracavitary and interstitial treatment of cancer. The University is authorized to possess and use a cobalt-60 teletherapy unit under NRC License No. 24-00063-10 in Jewish Hospital and two self-shielded cesium-137 blood irradiators, under NRC Licenses No. 24-00063-13, and 24-00167-13.

The radiation safety program is conducted under the direction of the Radiation Safety Officer (RSO) John Eichling, Ph.D., and all uses of licensed material are done with the approval of the Radiation Safety Committee (RSC). There are currently 390 authorized users of licensed materials, 900 areas of use, 2200 workers actively involved in the use of licensed materials and over 10,000 orders for licensed material are placed and received annually. Since the last inspection, the RSC has reviewed and approved 31 applications for use of licensed material.

4. Inspection History

An area of concern from the last inspection questioned whether adequate evaluations were being done by the RSC of potential radiation safety hazards involved in experimental protocols. The licensee has begun a new initiative to improve the evaluation of potential radiation safety hazards involved in experimental protocols. This consisted of adding a general request to the applicant interview form to describe any procedures or handling techniques that may result in unusual radiological safety concerns. The person who performs the interview is required to specifically address this question during the interview. This initiative was begun in January 1993 and applied to all new applications for use. The inspectors observed that one potentially hazardous procedure using licensed material in a proposed experiment was brought to the attention of the review committee and extensive additional review of the proposed procedures was done as a result of the new initiative.

Another area of concern from the previous inspection concerned the practice of persons eating and drinking in laboratories where radioactive material is used. The licensee has initiated a new program based on an amendment to the license which allows certain laboratories, where small quantities of radioactive materials are used, to have "clean

areas"established and approved by the radiation safety office. This program has only recently been instituted (October 1993). Random checks of several laboratories indicate marginal success in that a coffee cup was found in one laboratory which had not been declared as a clean area. The inspectors stated at the exit meeting that user cooperation would be essential for the program to be successful and suggested that management must clearly communicate its expectations with the staff.

This area of concern will be reviewed during the next inspection.

5. Internal Audits and Surveys

The licensee is required by conditions of its license and by 10 CFR Part 35 to perform certain internal audits and surveys. This inspection was largely directed at the medical uses of byproduct materials at the University Hospitals. 10 CFR 35.70(a) requires a survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered. As of November 18, 1993, the licensee failed to conduct a survey with a radiation survey instrument at the end of each day in the cesium room at Barnes Hospital where iodine-131, phosphorus-32, and strontium-89 are routinely prepared for use. The failure to provide this survey is an apparent violation of 10 CFR 35.70(a).

10 CFR 35.70(b) requires that the licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

As of November 18, 1993 the 9th floor Pavilion of Barnes Hospital Radiopharmaceutical waste storage room and the cesium room at Barnes Hospital have not been surveyed weekly with a survey instrument as required by 35.70(b) nor have they been surveyed for removable contamination once each week as required by 35.70(e). The failure to provide this survey is an apparent violation of 10 CFR 35.70(b) and 35.70(e).

These apparent violations appear to be caused by an oversight in not having these areas included in the routine survey program. Other similar areas were included in the survey program.

Two apparent violations of NRC requirements were identified in this area.

6. Training

Four hour lectures are provided to all individuals who handle licensed materials, unless the individual can show evidence that training and

experience precludes the necessity for additional training. Approximately one-half of the applicants are able to show such evidence. All individuals are required to pass an examination covering the material provided in the lectures and the training manual. Annual retraining is provided in the form of written material which goes to each authorized user who distributes the materials to staff. The staff is required to sign the material indicating that they have read and understand it. The inspectors reviewed training records and discussed the program with the radiation safety staff. Training appeared to be adequate in all areas except as described below.

The inspectors reviewed the licensee's training program with respect to emergency training for the Health Physics staff, technicians, and users. The inspectors believe, based on the event which occurred on May 5, 1993, involving the rupture of an ytterbium-169 sealed source and discussions with authorized users and radiation safety staff, that more emphasis on this aspect of the training and retraining is needed. Those persons who appear to be particularly in need of such training are those persons who are responsible for the handling of potentially hazardous quantities of materials such as sealed sources not housed in permanent shielded environments, iodine-131, iodine-125, and phosphorus-32. This was discussed with several of the radiation staff as well as the RSO, and was discussed at the Exit Meeting on November 18, 1993. The inadequate job specific training at Washington University regarding proper response to emergency situations is of concern to the NRC.

An inspector reviewed the training provided to personnel who operate the remote afterloaders and who attend brachytherapy implant patients and radiopharmaceutical therapy patients. These individuals include brachytherapy technologists, physicists, residents, medical authorized users, and nurses on floors 4400 and 7400. A review of training records and several interviews with appropriate personnel revealed that these individuals have been trained as required and appear to understand the routine operation of the devices and emergency procedures. Two exceptions to this was nurse training in the use of the video monitors to observe brachytherapy patients during treatment and staff training in restrictions on visitor access to brachytherapy rooms. These exceptions are further discussed in Section 7 of this report.

One concern was identified for License No. 24-00167-11.

7. Incidents and Misadministrations

Since the last inspection, five incidents have occurred: the first and second were misadministrations; the third concerned a patient who died while receiving remotely afterloaded brachytherapy treatment; the fourth involved a patient interrupting treatment in a state of distress by self removal of sources and attempted to leave the treatment room; and the fifth occurred when a brachytherapy source was ruptured. Four of the five incidents involved low-dose afterloaders. The inspectors focused on these incidents during this inspection.

The first two incidents occurred on January 7, 1993, and February 26, 1993. The first incident occurred during the administration of a single pre-operative intracavitary implant to a patient using a "MicroSelectron" Low-Dose-Rate remote afterloading device (SN 3031). The device ejected a radioactive source (8.6 mgRaEq Heyman-Simon Cs-137 source), without the device being programmed to do so and without the applicator attached to the corresponding "umbilical tube orifice." The source lay near the patient's leg for approximately five minutes at an approximate distance of three centimeters from the nearest skin surface. The licensee estimated that less than 0.1 rad of additional dose was delivered to the skin surface.

The second incident, which occurred on February 26, 1993, was very similar to the first. It also involved the administration of a single pre-operative intracavitary implant, using the same remote afterloading device (but to a different patient). The device again ejected the same strength and type of radioactive source, without being programmed to do so. However, in this case, the source lay near the patient's leg for approximately sixty to seventy-five minutes, at an approximate distance of five centimeters from the nearest skin surface. The licensee estimated the additional dose to the unintended treatment site to be approximately 3.5 rad. In both cases, the treatment of each patient was completed on another low-dose-afterloading device in another room of the medical center.

Documentation of the two events were sent to Region III at the request of the NRC following discussions by telephone. This documentation was reported to NMSS Headquarters and reviewed by the NRC Region III and NRC Headquarters staff. Based on the information provided, the incidents were determined to be misadministrations. Section 35.2(5)(i) of 10 CFR includes as a misadministration, "a brachytherapy radiation dose involving the wrong patient, wrong radioisotope, or wrong treatment site." It was concluded that even though the doses received were below the threshold of significant consequence, the two events were misadministrations. The inspectors noted that the cause of the misadministrations was equipment error.

As a followup to the two misadministrations, Region III sent a letter dated September 23, 1993, to the licensee which detailed its determination in the incidents and requested that the licensee review each case to determine whether required notifications had been made pursuant to 10 CFR 35.33. These included the verbal as well as written followup notifications to the patient and referring physician. The response received from the licensee, stated in part, that the referring physician and the treating physician had, based on their medical judgment, concluded that providing further information to the patients would be harmful to them. It is the licensee's position that because the verbal notification occurred prior to recognizing the incidents as misadministrations, the patients have not been notified in accordance

with 10 CFR 35.33(3). A letter dated November 23, 1993, was sent to the licensee requesting additional information as to the reason for not notifying the patients in writing. The licensee's response dated December 8, 1993, provided additional description regarding the medical basis for not notifying the patients. In summary, this letter states that both physicians believe, in their best medical judgement, that sending written notifications of these incidents, several months after they took place, will cause increased psychological stress and anxiety to the patients. The licensee also holds the opinion that the events have no medical significance to these patients since the doses were very small and the patients are of an advanced age. This matter is still under NRC review.

After the first incident on January 7, 1993, in which an un-programmed source was ejected by the afterloader, Washington University physicists contacted the manufacturer who dispatched a field engineer to St. Louis who studied the device malfunction. The engineer did not identify the cause of the failure during this visit. Washington University physicists and electronics staff subsequently tested the device for 20 hours and deemed it fit for use without discovering the cause of the failure. This decision was based on the fact that they could not reproduce the malfunction. When the remote afterloader was put back into service, on February 26, 1993, the device failed again in that an un-programmed source was ejected by the afterloader. After this incident, which resulted in another misadministration, the manufacturer provided a different field engineer who correctly diagnosed the problem as a failure in an operational amplifier.

It was also determined that a previous recommendation to store unused sources in the afterloader instead of the auxiliary storage safe may have contributed to the incident. The licensee learned from the field engineer that when unused sources are stored in the afterloader some of the normal safety features which are designed to prevent the programmed sources from being ejected do not apply to the un-programmed unused sources.

The inspectors were informed of a recommendation made by the manufacturer, prior to the January 7, 1993 incident, that the unused sources be stored in the afterloader. This procedure was adopted by the licensee. At the time the recommendation was implemented, the licensee did not understood that following this recommendation would eliminate certain safety features regarding the sources stored in unprogrammed locations. This recommendation provided by the manufacturer was to reduce wear on the source retrieval devices which had been redesigned by the manufacturer after a number of failures had occurred which resulted in the sources not always being retrieved. The manufacturer attributed these source retrieval failures to the unique way in which the licensee uses the afterloader device.

There appears to have been an inadequate analysis of the cause of the first incident which may have resulted in the device being placed back into service with the potential for another similar event to occur. The technical recommendation of the manufacturer for the licensee to store unused sources in the afterloader rather than in the associated source safe during treatment appears to have contributed to the incidents. In a teleconference on January 3, 1994, between Jeffery Williamson, Chief Brachytherapy Physicist and John A. Grobe, Section Chief, Section 2, Materials Inspection, NRC Region III, it was stated by Dr. Williams, that the two MicroSelectron-LDR units will be returned to Nucletron and a new model LDR unit will be installed at Washington University.

The third incident reviewed by the inspectors concerned a patient who on June 27, 1993, was discovered to have died while undergoing treatment for vaginal carcinoma using a low-dose afterloader at Barnes Hospital. The inspection confirmed that there was not a misadministration in this case because the patient did receive the correct amount of dosage; however, the circumstances of the death of the patient raised questions regarding nurses training in use of the video monitor system required by the license.

The attached follow-up report from the licensee dated July 12, 1993, states that it appears that the patient's condition had not been checked between 01:36 a.m. and 05:21 a.m. when the afterloader alarm sounded the morning that she died. The reason that the alarm had gone off was because the treatment period had ended, but the sources had not returned to the afterloader because the guide tube was damaged as a result of the patient falling out of the bed. The inspectors confirmed that the video monitor had not been used for viewing the patient during the early morning shift. Condition 25. of the License No. 24-00167-11 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in a letter dated April 18, 1988, which states "Patient viewing is available via video camera and monitoring systems. If patient viewing is not available then treatment will be halted." This is an apparent violation because in this event, it was determined that no one was posted at the nursing station where the monitors were located and therefore patient viewing was not available and treatment was not halted.

The inspection also disclosed through interviews with nursing staff, that it had not been impressed on the nursing staff that the use of the monitors was required at any particular interval. Failure to impress on the nursing staff that the regular use of the video monitors to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problem with the afterloading device is of concern to the NRC.

The fourth incident that was investigated involved an incident reported to Region III on October 23, 1993. On October 22, 1993, at 3:25 pm, a patient received less than the prescribed dose while undergoing

treatment for endometrium cancer using a LDR Afterloading device. The patient forcibly removed the implant and wandered around the treatment room approximately 5 minutes before opening the door to the treatment room in a state of distress. This incident was not considered a misadministration due to patient intervention. However, this incident as in the third incident, again raises a question regarding the adequacy of monitoring of patients undergoing this type of treatment. The inspectors note that in addition to the video monitoring, the beds have alarm systems which could alert nursing staff of a patient leaving the bed. However, this system had not been activated.

The fifth event occurred on May 5, 1993, and involved the rupture of an ytterbium-169 sealed source manufactured by Medi-Physics, Inc. in the Cesium laboratory at Barnes Hospital. The sealed source was a 2.8 millicurie Yb-169 seed wire core encapsulated in a titanium capsule. The source was being used in authorized experiments in a brachytherapy laboratory. The source had been placed in a phantom for an experiment. Upon removing the source from the phantom, it was observed that the source had become bent. The authorized user called Radiation Safety and requested a leak test. A technician from Radiation Safety performed a leak test on the source properly by placing the source behind a transparent shield in the cesium room of Barnes Hospital. However, he was asked by the authorized user if he could straighten out the source using his tweezers. The technician agreed to do this and when the attempt to straighten the source was made, the source broke into two halves. Condition 19. of License No. 24-00167-11 states that sealed sources containing licensed material shall not be opened. The inadvertent opening of the sealed source constitutes an apparent violation.

The attempt to straighten a bent source by the technician was not described in a procedure reviewed and approved by the radiation safety committee. Although contamination from the broken sealed source was minimal and no contamination was apparently spread as a result of the incident, had this occurred with some other sealed sources there could have been a serious contamination of personnel and the laboratory. Following the rupture of the sealed source, no contamination survey of the laboratory was performed. The inspectors believe that the RSC should have been asked to review the proposed repair of the source and that any such request should receive very careful review of the safety considerations.

The Authorized User stated that it was his assumption that the Radiation Safety Staff person sent to leak test the source was expert in handling sealed sources and was authorized to perform the task of straightening the bent source. The Radiation Safety technician and the RSO both stated that it was their assumption that the Authorized User was expert in handling the sealed source and therefore were relying on his judgement on handling the sealed source. This event has prompted two areas of concern which appear to be directly related to inadequate job

specific training: (1) A technician responsible for the routine leak tests of sealed sources apparently did not fully understand the hazards associated with tampering with sealed sources; and (2) Once the source was broken inappropriate emergency action was taken to ensure that spread of radioactivity had not occurred.

One additional incident was investigated during the inspection. On July 24, 1993, a patient was receiving interstitial brachytherapy treatment with the MicroSelectron/PDR (pulsed dose rate) remote afterloading system. On July 25, 1992, the chief brachytherapy physicist was contacted and informed that two of the patient's visitors were concerned that they had been exposed to radiation when they had visited the patient on July 24, 1992.

The physicist investigated the incident and discovered that on July 24, 1992, a unit clerk told the visitors that they could visit the patient. The visitors opened the treatment room door and closed it behind them. A nurse discovered the visitors and asked them to leave the room, closed the door and operated the controls of the PDR. She then allowed the visitors to continue the visit. The visitors were aware that the nurse had operated the controls after they left the room and before they were allowed to re-enter and subsequently became concerned that they might have been irradiated.

The physicist interviewed the visitors and reviewed the PDR computer generated treatment log. He concluded that when the visitors entered the room the first time the source was in its shielded position and by opening the door they effectively interrupted the controls so that the source would not have come out except when reset by a nurse. Based on interviews with the visitors, the nurse, and a review of the treatment log, he concluded that the visitors had not been irradiated, however, he concluded that 2 procedures were violated. Only nursing personnel are permitted to interrupt the treatment to admit visitors, and when staff or visitors are present in the treatment room, the door must remain open.

Corrective actions involved submitting a memorandum to the nursing floor supervisor regarding the incident. The inspectors were informed that unit clerks are not required to attend radiation safety training regarding procedures and policies for use of radioactive materials and it appeared that the unit clerk had not received instruction of visitor procedures before or after the incident.

Condition 25 of License No. 24-00167-11 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in a letter dated July 18, 1991. The letter dated July 18, 1991, states, in Item V.C.3., that only visitors and hospital workers authorized by trained nursing staff are allowed to enter the brachytherapy treatment area. On July 24, 1992, visitors

who were not authorized by a trained nurse, were allowed to enter the brachytherapy treatment area. An untrained unit clerk allowing visitors to enter a restricted area is an apparent violation of Condition 25 of License No. 24-00167-11.

Even though the licensee identified the violation prior to the inspection, the inspectors concluded that the corrective actions taken were not comprehensive and would not reasonably prevent recurrence.

The safety significance is mitigated at this time because the licensee, for unrelated reason, has voluntarily discontinued use of the PDR remote afterloader for an unspecified period of time. In addition, the licensee does have specific procedures in place, and has trained nurses on these procedures. These procedures require that prior to operating the remote afterloaders, the trained nurse must assure that only the patient is in the room. In addition, the units are interlocked such that if a visitor entered the room and closed the door the interruption of the interlock would not allow the source to come out of the shield until the control console was reset by a trained nurse who is required by the procedure to check the room for the presence of any other individual.

Three apparent violations of NRC requirements were identified for License No. 24-00167-11.

Five concerns were identified for License No. 24-00167-11 associated with incidents and misadministrations.

8. Other Areas Inspected

The inspectors also interviewed personnel, reviewed bioassay records and results, other incidents involving radioactive materials, quarterly radiation safety audits, procedure demonstrations by personnel, QMP records for iodine-125 and iodine-131 (less than 30 mCi) administrations, waste storage areas, decay-in-storage disposal records, transportation, receiving packages and transfer of radiopharmaceuticals, surveys, authorized users, xenon-133 uses, room ventilation measurements, postings, safe uses and emergency response procedures, facilities, dose calibrator tests, survey instrument calibrations, leak tests, inventories, and patient dose logs. No violations were identified in these program areas.

The inspectors identified one area of concern while inspecting the medical program. Area surveys performed with a radiation detection survey meter in the nuclear medicine department, 9th Floor West Pavilion, Barnes Hospital, were only being performed at the center of each room. Routine weekly contamination swipe tests indicated that contamination was periodically found when wipe tests were conducted. Daily surveys should be performed adequately enough to detect

radioactive material contamination and when found, should be decontaminated at once, rather than having a 7-day interval to pass before radioactive material contamination is identified. Procedures followed in the performance of area surveys and weekly contamination tests are an area of concern to the NRC.

The two self-shielded irradiators Licenses No. 24-00063-13, and 24-00167-13 were also inspected. No apparent violations were identified pertaining to these licenses.

One area of concern was identified for License No. 24-00167-11 (broadscope).

9. Teletherapy/License No. 24-00063-10

An inspector performed a routine inspection of the licensee's cobalt-60 teletherapy program.

10 CFR 35.634(d)(6) requires that a licensee authorized to use a teletherapy unit for medical use perform safety spot-checks once in each calendar month that assure proper operation of electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

The inspector determined based on interviews and a review of records, that as of November 18, 1993, the licensee failed to include in monthly safety spot-checks tests that assure the proper operation of electrically assisted treatment room doors with the teletherapy unit electrical power turned off. Failure to test the operation of the electrically operated door with the power to the teletherapy unit turned off is an apparent violation of 10 CFR 35.634(d)(6).

The chief teletherapy physicist stated that he was unaware of this requirement. He stated that the power to the teletherapy unit and the power to the electrically operated door are supplied by independent circuits and loosing power to the teletherapy unit should not cause a loss of power to the door. However, he agreed that this was not specifically verified on a monthly basis.

In addition, the inspector expressed a concern that teletherapy physicists and oncologists are not included in the annual teletherapy emergency drills and do not receive specific instructions on this institution's policies and procedures regarding stuck teletherapy sources. A technologist stated that if the source failed to retract she would remove the patient from the room and call a physicist or oncologist. Since a physicist or oncologist may need to respond to a stuck source, they should be provided adequate training so as to assure that the institution's policies are followed and safety is maintained.

During the inspection, the inspector attempted to open the electrically powered treatment room door with the power to the door turned off. The inspector was unable to open the door sufficiently due to the hydraulic pressure in the door opening mechanism. The inability to open the treatment room door with the power to the door turned off is of concern to the NRC. This concern was discussed with the chief teletherapy physicist, the chief technologist, and with management representatives during the exit meeting.

One violation of NRC requirements was identified for License No. 24-00063-10.

Two concerns were identified for License No. 24-00063-10.

10. Exit Meeting

At the conclusion of the inspection on November 18, 1993, the inspectors met with those individuals identified in Section 1 of this report. The inspectors summarized the areas inspected, the apparent violations, areas of concern, and discussed the forthcoming letter. The licensee did not identify any information provided during the inspection as proprietary.