ENCLOSURE

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

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Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY
Department of Veterans Affairs Medical Center
West Los Angeles
NRC Inspection Report 030-22280/96-01

This special, announced inspection included an evaluation of licensee activities relating to a malfunction of a cobalt-60 teletherapy unit. The malfunction involved an intermittent failure of the source drawer to move the source into the exposed position. The inspectors reviewed actions taken by licensee personnel following the first and subsequent failures of the source drawer. Also reviewed were diagnostic and repair efforts by the manufacturer of the teletherapy unit, Theratronics International, Ltd.

Program Overview

- The Department of Veterans Affairs Medical Center, West Los Angeles (VALA or licensee) is authorized to use a Theratron Model 780 teletherapy unit and has performed approximately 15 patient treatments daily with this unit. The teletherapy unit is approximately 23 years old and has been serviced for routine maintenance at regular intervals (Section 1).

Effects on Patient Treatments

- The potential effect of the teletherapy unit malfunction on patient treatments was evaluated by the license and was determined to be minimal. The licensee determined that had such a failure occurred and gone undetected during a patient treatment, the failure could only have resulted in an underdose (Section 3).

Diagnosis of the Cause of the Teletherapy Unit Malfunction

- The teletherapy unit manufacturer identified a loose wire and failed circuit board which may have contributed to or resulted in the failure. A complete diagnosis and root cause analysis had not been completed as of January 2, 1997 (Section 4).

Corrective Actions

- The licensee completed several corrective actions including implementation of additional procedural controls, providing training to the staff, and installation of new teletherapy unit components (Section 5).

Quality Assurance and Maintenance

- The licensee had performed routine quality assurance testing and maintenance on the teletherapy unit. Discussions with licensee and Theratronics personnel and review of licensee records revealed no unusual or unexpected problems prior to November 27, 1996 (Section 6).

Confirmatory Action Letter (CAL) and Written Reports To the NRC

- On December 10, 1996, and January 2, 1997, the NRC issued Confirmatory Action Letters documenting several actions to be taken by VALA, including implementation of procedural controls focused on prompt identification of source drawer failures, determination of the exact cause of the failure, and determination of whether the unit could continue to be used safely in the long term (Section 7).

Report Details

1 Program Overview (87103)

1.1 Inspection Scope

The inspectors reviewed the license docket file, teletherapy unit quality assurance and maintenance records, and previous NRC inspection findings. The inspectors also conducted interviews with VALA staff in the radiation therapy service and a Theratronics service representative.

1.2 Observations and Findings

The VALA is a medical facility involved with clinical, therapeutic and research activities authorized under two NRC licenses. The broad-scope license authorizes use of diagnostic and therapeutic radiopharmaceuticals, brachytherapy procedures and research activities. The second license authorizes use of a cobalt-60 teletherapy unit and its associated depleted uranium shielding for radiation therapy. The 23-year old teletherapy unit is a Theratron Model 780 containing approximately 4500 curies of cobalt-60 and had been used to treat an average of 15 patients per day.

The teletherapy unit is operated by one of four rotating radiation therapy technologists (therapists) who are supervised by one administrative technologist. There are four radiation oncologists (physicians) who serve as authorized users and are named on the NRC license. One of the authorized users is the Chief of the Radiation Therapy Service, serves as the radiation safety officer (RSO), and is a member of the radiation safety committee. In addition, there are two teletherapy physicists (physicist) also named on the license who are routinely assigned to the department and perform radiation therapy dosimetry and radiation safety duties.

2 Teletherapy Unit Malfunction Sequence of Events (87103)

2.1 Inspection Scope

The inspectors interviewed personnel and reviewed teletherapy use records to reconstruct events associated with the failures of the source drawer mechanism.

2.2 Observations and Findings

The following is a chronological sequence of events associated with the teletherapy unit source drawer failures and actions taken by the licensee and manufacturer.

- November 27, 1996: While performing a routine, weekly light-to-radiation field comparison test, a physicist noticed that the source drawer mechanism failed to move the cobalt-60 source into the exposed (beam on) position when the digital timer was activated. A second attempt to activate the source drawer

was successful and the test was completed indicating proper light-radiation field alignment. The physicist reported the failure to a second physicist who subsequently activated the timer and source drawer twice with no problems noted. All VALA staff members interviewed by the inspectors stated that they did not recall experiencing any problems with activation of the source drawer prior to the physicist's test on November 27. No problems were encountered with the teletherapy unit during patient treatments earlier in the day on November 27.

- Morning of November 29, 1996: The daily (early morning) pre-operational checks and two patient treatments were conducted with no problems noted. Treatment was then initiated on a third patient at approximately 9:30 a.m., and the first two of three planned treatment fields were successfully treated. Upon activation of the timer to begin treatment of the third field, the therapist noticed that the radiation monitor located to the right of the console was not registering radiation as expected (i.e., the indicator needle on the meter was registering background radiation levels). The therapist interrupted the treatment timer, entered the teletherapy room and removed the patient. The therapist then notified the physicist who arrived at the teletherapy console a few minutes later and despite several attempts, was unsuccessful in duplicating the malfunction just observed by the therapist.

  The physicist called Theratronics and described the problem. Theratronics representatives advised the physicist that if the source drawer failed to activate, it would be an "all or nothing situation" (i.e., either the source drawer would completely activate and produce a full radiation field as intended or there would be no activation and no radiation). Based on this information from Theratronics and after discussing the problem with one of the licensee's authorized users, the physicist decided to authorize resumption of treatments. The physicist instructed all therapists to be vigilant in checking that all indicators (i.e., lights, radiation and closed circuit television [CCTV] monitors) functioned as expected when the timer was activated. The physicist also instructed the therapists to use a special radiation detecting diode, located on the teletherapy patient couch, to provide an integrated dose readout on a meter near the console. (This would allow the staff to confirm that the source was in the exposed position throughout the intended treatment time.)

- Afternoon of November 29, 1996: Prior to initiating a patient treatment, a therapist attempted to complete two port films (a total of five exposures). The timer was set at 0.03 seconds and appeared to operate normally upon activation; however, the radiation monitor indicated only background radiation levels, as though the source was not in the exposed position. When developed, none of the films showed any exposure and the diode did not register any radiation dose. This prompted the physicist to make a second call to Theratronics representatives who then contacted a service technician and directed him to travel to VALA and perform the needed diagnosis and repair.

The physicist and authorized user subsequently decided to terminate further patient treatments for the day.

The physicist then repeatedly tested the teletherapy unit and noted additional intermittent source drawer mechanism failures. At about 2:15 p.m., the physicist called the NRC Region IV Walnut Creek Field Office and left a voice mail message concerning the teletherapy unit problem.

- November 30 through December 1, 1996: The teletherapy unit was not used for any purpose.

- December 2, 1996: The routine early morning quality assurance tests were performed on the teletherapy unit by a therapist and no source drawer problems were noted. At approximately 10:30 a.m., the Theratronics service technician arrived at the VALA.

  With the physicist and Theratronics technician observing, a therapist completed a port film and a patient treatment without problems. By 2:30 p.m., all patient treatments for the day had been successfully completed with no problems noted. The Theratronics technician then began a series of approximately 100 repetitive tests of the timer and source drawer and was able to duplicate a failure three or four times. The technician inspected and tested various mechanical and electrical components on and inside the teletherapy unit.

  Late in the afternoon of December 2, the technician continued repetitive testing of the timer and source drawer and noted another instance where the timer started but the source failed to move. However, in this case, after 5-6 seconds, the source drawer unexpectedly activated and moved into the exposed (beam on) position. The technician described this anomaly to the physicist and authorized user who then decided to terminate further patient treatments.

- December 3, 1996: No patients were treated. The technician continued to perform mechanical and electrical testing and inspections and discovered a loose wire connection within the teletherapy unit head electrical circuits. With the wire completely disconnected, the timer could still be activated and began to count but the source drawer solenoid received no electrical signal and the source drawer did not move. By replacing the wire in its loose but semi-connected configuration, the technician was able to duplicate the source drawer failure several times out of perhaps a hundred tests. It appeared that the loose wire made intermittent contact allowing circuit completion and source drawer solenoid activation approximately 95 percent of the time. The loose wire connection was configured as a "spade" connector. The "spade" portion of the wire did not fit tightly into the grooved connector allowing the "spade" to easily slip out of the connector or at least make poor electrical contact. The technician tightened (crimped) the groove and reconnected the wires securely.

- December 4, 1996: No patients were treated because the technician discovered that the light field electrical cord and reset button needed servicing due to excessive wear. Region IV notified VALA that two NRC inspectors and a U.S. Food and Drug Administration (FDA) representative would be arriving at the VALA on December 5, 1996.

  Region IV confirmed with the licensee's Acting Radiation Therapy Chief that the teletherapy unit would not be used for patient treatment until authorized by a Region IV manager. NRC Region IV management contacted Theratronics management to arrange a telephone conference call for December 5 with the NRC Office of Nuclear Materials Safety and Safeguards (NMSS), FDA and Region IV.

- December 5, 1996: Two NRC inspectors and an FDA electrical engineer arrived at VALA. The NRC inspectors began interviews with licensee personnel and reviewed records related to the teletherapy unit operation and maintenance.

  A conference call was conducted during the afternoon with representatives from NMSS, Region IV, Theratronics, FDA, and the licensee. A Theratronics representative discussed the source drawer failure, efforts taken to diagnose the cause and the discovery of the loose wire. Theratronics also discussed operation of the timer and the source drawer and confirmed that the timer would continue to operate even if the source drawer failed to move. Theratronics representatives noted that activation of the timer mechanism provided a signal to the source drawer solenoid; however, the single channel timer installed on the VALA unit operated independent of the source drawer. The source position indicator lights on the console were electrically connected to the source drawer and dependent on the source position. Thus, although the timer could continue to count even if the source drawer failed to move, the console and room radiation indicators should have provided a valid indication of the source position.

  An updated "dual timer" designed to replace older single channel timers was also described by Theratronics. The dual timer was designed to monitor both the source drawer movement and total elapsed treatment time and alarmed if the source drawer movement did not initiate when the timer was activated. A Theratronics representative noted that newer teletherapy units (those manufactured after 1985) were equipped with the dual timer and that the company had previously informed its customers of an upgrade that was available to replace an older single channel timer with a dual timer. The manufacturer's representative further noted that replacing the single channel timer with the dual timer would provide additional notification to the user if the source drawer failed to move upon activation.

- December 6, 1996: The NRC inspectors and FDA representative continued with interviews of licensee personnel and observed diagnostic tests conducted on the teletherapy unit by the Theratronics technician. Region IV managers and VALA managers discussed VALA's proposed actions and agreed that VALA would notify the Region IV office to discuss diagnostic efforts and repair of the unit prior to using the teletherapy unit for patient treatments. Repeated tests by the technician and physicist of the timer and source drawer mechanism were conducted with no sign of malfunction. It was subsequently assumed by Theratronics and the licensee that the repair of the loose wire connection had corrected the problem.

  Following further discussions with NRC staff, the licensee's physicist and authorized user confirmed in writing that the therapists would be trained on a revised teletherapy treatment procedure. The licensee's written submittal included a copy of the modified procedure which provided specific instructions on monitoring visual indicators on the teletherapy unit control console and room radiation monitors during patient treatments. The licensee's submittal stated that training on the new procedure was to be completed prior to the resumption of patient treatments.

- December 9, 1996: The licensee's physicist notified Region IV that treatments had been resumed (without notification to Region IV) and that the source drawer failure was observed again on three occasions on December 9. The physicist stated that he had requested that Theratronics send the service technician back to VALA to further investigate the cause of the source drawer failure. When questioned about why VALA had not discussed with Region IV management its intent to resume patient treatments with the teletherapy unit, the physicist stated that he had completed training all therapists as stated in his December 6 correspondence and was under the impression that the unit could be used for patient treatments.

  A telephone conference call was subsequently held with Region IV staff and the licensee. VALA representatives informed Region IV that 10 patients had been treated with the teletherapy unit on December 9. The first two source drawer failures occurred during an attempt to take a port film. As before, the timer operated upon activation but the source drawer did not move. A second attempt to take the port film was successful. The physicist responded and while repeatedly testing the unit, the source drawer failed to move again.

  Following discussions with Region IV management, VALA representatives committed to immediately discontinue further use of the teletherapy unit including the cessation of all tests and port film exposures. VALA representatives also agreed to delay diagnostic testing of the teletherapy unit until an NRC inspector and FDA representative were present to observe further investigation and repair of the unit and that a written report of the results of the investigation and proposed repairs would be provided to the NRC.

- December 10, 1996: The NRC issued a Confirmatory Action Letter (CAL) to the licensee confirming the actions noted above.

  At 11:30 a.m., the inspector arrived at the VALA and met with the FDA engineer and Theratronics technician. The RSO for the licensee's broad-scope NRC license was also present. The technician continued to test electrical circuits in an attempt to isolate what he believed was an electrical problem. At approximately 4 p.m., the technician replaced a circuit board believed to be defective. However, when initially tested with the new circuit board installed, the teletherapy unit again failed to move the source drawer upon timer activation.

- December 11, 1996: Further testing was performed by the Theratronics technician, and no failures were observed. The licensee and technician decided to reinstall the old and apparently defective circuit board to see if the failure returned. Repeated testing continued throughout the day with no sign of failure. Late in the day the new circuit board was reinstalled.

  Discussions were held between the technician and physicist regarding the replacement of the old single channel timer with a new dual timer. The technician explained operation of the dual timer and noted that its use should result in safer operation even if the source drawer problem continued. With the dual timer, one channel counts elapsed time beginning with activation by the teletherapy unit operator, and a second timer keeps track of the elapsed time once the source drawer completes its movement to the exposed (beam on) position. If the source drawer fails to activate within 2.5 seconds, the second timer does not start and an error message and an audible alarm are triggered. Further operation would be prevented until the unit was reset with a key activated switch.

- December 12, 1996: The teletherapy unit was not operated. Theratronics and VALA representatives discussed installation of a new dual timer. Installation and testing was estimated to require two days.

- December 13, 1996: A conference call was held with the licensee, Theratronics, NRC and FDA to discuss the apparent cause of the teletherapy unit malfunctions and possible generic implications. Theratronics representatives summarized attempts made to identify the cause of the source drawer failures and subsequent repair attempts. Theratronics representatives committed to conduct further diagnostic tests on the failed circuit board at Theratronics' facilities in Canada. Theratronics representatives also noted that the service technician was unable to reproduce the source drawer failure with the new circuit board installed and stated that they did not believe that the failures observed with this system were indicative of a potential generic problem with other Theratron Model 780 units.

The licensee sent a letter dated December 13, 1996, to the NRC Region IV Regional Administrator describing attempts to define the cause of the teletherapy unit problems and the corrective actions planned. A description of the dual timer installation and use was also included along with a commitment to have further testing of the circuit board performed by Theratronics. The licensee requested authorization to allow Theratronics to install and test the dual timer followed by resumption of patient treatments once Theratronics declared the teletherapy unit fully operational.

- December 23, 1996: The licensee informed Region IV that the dual timer installation was completed; however, the reset switch needed replacing. Theratronics planned to install a new reset switch and anticipated the teletherapy unit would be fully operational by December 24.

- December 24, 1996: After confirming that installation of the timer and reset switch and testing had been successfully completed, NRC Region IV issued a letter to the licensee authorizing resumption of patient treatments with the teletherapy unit.

- December 27, 1996: At 11:55 a.m. (PST), the licensee's physicist notified Region IV by telephone that on December 26, two source drawer failures occurred while attempting to treat patients. The dual timer functioned as designed and alerted the therapist operating the teletherapy unit of the failure. On the second attempt following each failure, treatment was successfully initiated and completed as prescribed by the authorized user.

- December 30, 1996: The physicist reported to Region IV that patient treatments were ongoing and no new failures of the source drawer had occurred since December 27. The physicist also reported that Theratronics was not planning to dispatch a service technician and had instead requested that the licensee document all teletherapy unit setup parameters associated with any future failures. The physicist emphasized that he believed that procedural controls and use of the dual timer were sufficient to alert the unit operators of future source drawer failures and that the problem would not result in inadvertent exposure of patients but rather a failure to expose the source.

- January 2, 1997: Following a telephone conference call with the VALA Chief of Staff, Region IV issued a supplement to the December 10, 1996, CAL documenting additional short and long-term corrective actions to be taken by the licensee.

3 Effects on Patient Treatments (83103)

3.1 Inspection Scope

During the week of December 2, 1996, the NRC inspectors conducted interviews of licensee personnel and reviewed records of teletherapy unit use to determine if any misadministration or other unintended radiation exposure could have occurred as a result of the source drawer failures.

3.2 Observations and Findings

The inspectors interviewed the four authorized users in the radiation therapy service to determine when they first became aware of the problem with the teletherapy unit and whether they believed any patient therapy treatments were adversely affected. All of the authorized users were made aware of the malfunction on November 27, 1996, and stated they did not notice any anomalous operations prior to this date. The authorized users added that post treatment examinations of their patients revealed no unusual or unexpected symptoms that would have indicated a problem such as an unintended over or underdose of radiation.

Similar interviews were conducted with the licensee's two teletherapy physicists and five therapists. Each employee was asked when he/she first learned that the teletherapy unit was malfunctioning and if he/she had noticed any unusual or unexplained operating conditions prior to November 27. No one could recall noticing any problems prior to November 27.

The first time a patient treatment was interrupted due to a source drawer failure was on November 29. The failure occurred when the therapist started the timer to complete the last of three planned treatment fields. As the timer began to count, the therapist noticed that the room radiation monitor was not indicating radiation levels above background. The treatment was terminated by the therapist and the patient was removed from the room. The patient's treatment was rescheduled and successfully completed as prescribed on December 2. The authorized user stated that the three day delay in delivering the final dose fraction resulted in no adverse medical consequences for the patient. No other patient treatments were delayed due to source drawer failures, although several patients were treated on linear accelerators on days when the licensee decided not to operate the teletherapy unit.

3.3 Conclusions

Based on interviews with authorized users and the radiation therapy service personnel who operated the teletherapy unit, the inspectors concluded that the first failure most likely occurred on November 27, 1996, and that no misadministration or unintended radiation exposure occurred. The authorized users concluded that no patient's treatment was adversely affected.

4 Diagnosis of the Cause of the Teletherapy Unit Malfunctions (87103)

4.1 Inspection Scope

The inspectors and the FDA electrical engineer spent several days observing the Theratronics technician attempting to diagnose the cause of and correct the teletherapy unit source drawer failures. Theratronics operation manuals and circuit diagrams were also reviewed.

4.2 Observations and Findings

During December 2-24, 1996, the Theratronics technician spent approximately two weeks at the VALA attempting to diagnose and correct the teletherapy unit problems. The technician activated that system 200-300 times and conducted numerous electrical circuit tests following activation of the timer. Through repetitive on-off cycling of the unit, the technician observed failure of the source drawer approximately 10 times. In two instances, the technician observed that the timer ran as expected while movement of the source drawer was delayed following activation of the unit.

As noted in Section 2 of this report, on December 3, 1996, the technician identified a loose wire connection which was initially thought to be the cause of the source drawer failure. However, after the connection was repaired, failure of the source drawer was again noted on December 9. During subsequent testing, the technician noted that the voltage in one circuit board, a silicon control rectifier (SCR), remained constant regardless of whether the source drawer solenoid was energized or not. The SCR controls the solenoids which operate the pneumatically controlled source drawer. The technician believed that the circuit board was defective and suggested to the licensee that it be replaced. The physicist concurred and the board was replaced with a new one. Following installation on the afternoon of December 10, the new circuit board was tested by the technician. During the first few repetitive timer activations, failure of the source drawer to move was again noted. However, following this initial failure, the timer was repeatedly activated hundreds of times during the following 3 days without reproducing the failure. The licensee elected to install a dual channel timer after the suspect circuit board was replaced on December 13, 1996. The dual timer was installed on December 23 to provide additional notification of source drawer movement failures and to provide a more accurate account of treatment (source exposure) times.

The unit was subsequently used without failure until December 26 when failure of the source drawer was noted twice. The licensee notified the NRC of the failures and it was agreed that VALA could continue to use the system for patient treatments, in the short term, provided that procedural controls implemented by VALA subsequent to the first failure were maintained. The VALA agreed to a request to notify the NRC of: (1) the results of further diagnostic testing of the system and suspect circuit board, (2) the cause of the source drawer failures,

(3) procedural controls to be implemented should failures recur, and (4) the licensee's long term plans for continued use of the unit. As of January 2, 1997, the licensee had not yet received results of testing performed by Theratronics on the circuit board and further testing of the teletherapy unit had not yielded additional information.

4.3 Conclusions

As of January 2, 1997, the exact cause of the teletherapy unit malfunctions had not been determined. Although continued use of the teletherapy unit was authorized by NRC staff, the licensee committed to ensure that further testing was conducted to determine the cause of the failures and to notify the NRC of its plans for future use of the unit.

5 Corrective Actions (87103)

5.1 Inspection Scope

The inspectors interviewed all staff members who operated the teletherapy unit to verify their training and experience and to evaluate their ability to recognize malfunctions of the teletherapy unit. Department procedures were also reviewed to determine whether they contained an appropriate level of detail regarding observation of the teletherapy unit console and room monitoring devices and source position indicators.

5.2 Observations and Findings

All of the therapists interviewed by the inspectors were experienced, registered radiation therapy technologists. Each was aware of the presence and meaning of the various teletherapy "beam on" indicators such as red warning lights, digital timer, radiation monitor, and source position indicator as viewed on the CCTV.

Following the initial discovery of the teletherapy unit malfunction on November 27, 1996, a teletherapy physicist implemented a supplementary procedure to be followed by the staff. The procedure was enclosed with a letter to the NRC dated December 6, 1996, and required that when initiating a patient treatment, therapists and authorized users: (1) ensure that the red light on the console panel is on; (2) ensure the green indicator light on the console panel is off; (3) observe the radiation monitor to verify that it is indicating the appropriate radiation level during the entire treatment time; (4) ensure that at the end of the treatment time, the red light is off and the green light is illuminated at the console panel; (5) ensure that the radiation monitor indicates a background radiation reading after the treatment time has expired; and (6) verify that the timer display matches the time specified in the authorized user's prescription (written directive). In addition, the procedure specified that at least one therapist must give undivided attention to items 1 through 6 above and avoid performing record keeping duties during patient treatments. To improve the viewing of the area radiation monitor, the licensee moved the monitor from a less

conspicuous position at the far right of the control console to a position above the center of the console and directly in front of where the unit operator normally sits or stands. During interviews with the staff, the inspectors verified that the physicist had reviewed the supplementary procedure with each therapist and that the therapists were maintaining the level of vigilance specified in the procedure.

In addition, as noted in Section 2 of this report, a new timer mechanism was installed on the teletherapy unit on December 23, 1996. While not intended to prevent future malfunctions, the new dual timer should enhance the therapists' ability to follow these supplementary procedures because it provides additional indication of a source drawer failure. Specifically, the timer provides an audible alarm if the source drawer fails to move the source within 2.5 seconds of activating the timer mechanism (which sends a signal to the source drawer) and requires that additional steps be taken (activating a key lock) to restart the system after a source drawer failure occurs. The licensee later supplemented instructions provided to the staff to require that therapists contact a physicist or the RSO if a source drawer failure occurred so that the failure could be investigated before patient treatments were resumed.

At the conclusion of the inspection on January 2, 1997, Theratronics was continuing to test the SCR to determine what electronic component, if any, had failed. As of January 2, 1997, the licensee's permanent corrective actions were unknown because the cause of the failure had not yet been determined.

5.3 Conclusions

VALA implemented additional procedural controls to emphasize the importance of monitoring source position indicators on the teletherapy unit and the room radiation monitor. The licensee also had a new timer mechanism installed on the teletherapy unit which provides additional indication of a failure to move the source to the exposed position. Although the cause of the failures had not yet been determined at the conclusion of the inspection, the licensee had taken steps to enhance the staff's ability to identify failures of the source drawer so that they would not go undetected and could be promptly investigated.

6 Quality Assurance and Maintenance (87103)

6.1 Inspection Scope

The inspectors reviewed aspects of the licensee's quality assurance program pertaining to the teletherapy unit safety systems. Interviews with the therapists and physicists were conducted and records were reviewed to evaluate the reliability and performance of the teletherapy unit interlock, radiation monitor, indicator lights, CCTV, and intercom. Records pertaining to the maintenance of the teletherapy unit were also reviewed.

6.2 Observations and Findings

The therapists and physicists conducted daily and monthly quality assurance tests to ensure that the teletherapy unit and related safety components were functioning as designed. The inspectors reviewed records of daily tests which included verification that the area radiation monitor, console and door "beam on" warning lights, and wall lasers were operating and examination of light-radiation field congruence. Interviews with licensee personnel and review of records indicated that these tests were performed early each morning prior to using the teletherapy unit for patient treatments.

More extensive tests were conducted once each month in accordance with 10 CFR 35.634. The inspectors reviewed records of these tests which included mechanical checks of the wall lasers, collimator field size and light-radiation field congruence. Safety checks included the door, console and teletherapy head warning lights, emergency off switches, door interlock, manual and electrical door operation, area radiation monitor, timer, CCTV, and intercom. Records of the required monthly tests were well maintained and current.

The teletherapy unit maintenance history records were reviewed by an inspector for the period from April 2, 1992, to October 10, 1996, (the date of the last servicing prior to the source drawer failure). Most of the maintenance was performed by an authorized Theratronics technician who responded to a specific request from the licensee for assistance with a problem. Typical problems that required service calls included an optical distance indicator that was out of alignment, a defective reset switch, hand controller circuit problems, cleaning and lubrication for various gears and other mechanical components, and an occasional failed circuit board. Occasionally, maintenance of components associated with, but not actually part of, the teletherapy unit was performed by the licensee's engineering department. Examples of this work included replacement of an interlock indicator light bulb and adjustment of the door/interlock interface. No maintenance or repair work related to the source drawer mechanism was identified.

6.3 Conclusions

The licensee's quality assurance program was implemented in accordance with 10 CFR 35.634. The licensee's quality assurance records, reviewed by the inspectors, did not indicate any problems with the teletherapy unit prior to November 27, 1996. A review of records documenting maintenance and repair of the unit since April 2, 1992, revealed no problems related to operation of the source drawer. Most of the maintenance and repair appeared to be a result of the teletherapy unit's age and extensive use.

7 Confirmatory Action Letter (CAL) and Written Reports to the NRC

7.1 Inspection Scope

This portion of the inspection involved the review of the licensee's actions taken in response to the CALs issued on December 10, 1996, and January 2, 1997.

7.2 Observations and Findings

As noted elsewhere in this report, the licensee first noted failures of source drawer to move the source during the week of November 25, 1996, and subsequently reported a problem with the Theratron 780 teletherapy unit to the NRC on November 29. Following additional failures and subsequent repair of a loose wire on December 3-6, the licensee assumed that the problem had been repaired and patient treatments were resumed on December 9. The VALA radiation therapy staff observed failure of the source drawer again during patient treatments on December 9, and the physicist subsequently notified the NRC of those observations. On December 10, 1996, the NRC issued a CAL to the licensee confirming that the licensee would: (1) secure the teletherapy unit to prevent tampering until a Theratronics service representative arrived to begin an investigation into the cause of the failures and NRC and FDA representatives were on site to monitor the investigation and subsequent repair activities; (2) provide to the NRC a copy of any written report submitted by Theratronics discussing the cause of the malfunction or recommended repairs, and prior to authorizing any repairs by Theratronics, ensure that the NRC and FDA have an opportunity to discuss the investigation findings and any testing of individual system components with the Theratronics service representative; (3) provide to the NRC a description of proposed repairs for the system as recommended by Theratronics or other parties providing service for the system; (4) provide a written report to the NRC Region IV office describing the cause of the malfunction and corrective actions including revised operational or procedural controls implemented by the licensee to ensure safe operation; (5) suspend all patient treatments with the teletherapy unit until the NRC and FDA reviewed the actions taken to repair the unit and agreed that the unit can be safely operated.

By letter dated December 13, 1996, the licensee replied to the CAL describing actions taken to address each item above. VALA stated in its letter that a circuit board (SCR) was determined to be the "major contributor" to the teletherapy source drawer failure. VALA also noted that the Theratronics service representative indicated that the timer mechanism may also have contributed to the problem, although VALA noted that since the failure could not be reproduced while the service representative was testing the system, they were unable to confirm this. VALA noted that repeated testing had been performed on the system in an effort to duplicate the failure and identify its cause. However, during the testing period, they were unable to duplicate the failure. VALA also stated its intent to have Theratronics perform further testing of the circuit board that was removed from the system and replaced and indicated that it planned to have a timer upgrade installed. This

upgrade was a dual channel timer which would provide additional confidence that if a failure occurred again, it would not go undetected. The medical center executive director also noted his intent to provide the NRC a copy of the Theratronics service reports once the circuit board had been tested.

Once the repair of the system was completed and the new timer was installed, VALA staff completed a routine monthly spot check of the unit to confirm that safety systems were operating as expected. The VALA notified the Region IV office by telephone on December 23 and 24 that repair and testing of the unit was completed. On December 24, 1996, the NRC issued a letter to VALA rescinding item 5 above, thus allowing the licensee to resume patient treatments with the teletherapy unit.

On December 27, 1996, VALA notified the inspector that additional failures of the source drawer were observed on December 26. According to the physicist, these failures appeared identical to those observed earlier in December and November. Although the new timer mechanism performed as expected, the observation of additional failures raised concerns that the cause of the problem had not yet been identified. Because of concerns regarding the true cause of the failures, the NRC issued a Supplementary CAL dated January 2, 1997, and following discussions with VALA staff, confirmed that VALA would: (1) within 10 days, provide a complete description of the operational and procedural controls to be implemented following any future source drawer malfunctions; (2) discontinue use of the teletherapy unit within 180 days and within 90 days provide a written analysis of the exact cause of the malfunctions and corrective action taken to prevent recurrence; (3) provide justification as to why the teletherapy unit could be used beyond 180 days from the date of the CAL; and (4) report further teletherapy unit malfunctions to the NRC within 24 hours of occurrence.

Exit Meeting Summary

The inspector presented the inspection findings to licensee management via telephone on January 2, 1997. No violations of NRC requirements were identified. The licensee acknowledged that some proprietary information (medical records) was made available to the inspectors during the inspection. The inspector noted that no proprietary information appears in the inspection report.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Licensee

A. Sadeghi, M.D., Chief Radiation Therapy Service and Radiation Safety Officer
B. Jabola, M.D., Radiation Therapy Service
L. St. Royal, M.D., Radiation Therapy Service
L. Tran, M.D., Radiation Therapy Service
B. Krutoff, Teletherapy Physicist
N. McCreary, Teletherapy Physicist
M. Landi, Radiation Therapy Technologist (therapist)
G. Ruckdaschel, Radiation Therapy Technologist (therapist)
D. Tran, Radiation Therapy Technologist (therapist)
R. Weaver, Radiation Therapy Technologist
O. Turner, Radiation Therapy Supervisor

Non-Licensee

D. Marquez, Service Specialist, Theratronics International, Ltd.
R. Alexander, Electrical Engineer, U.S. Food and Drug Administration
R. Nicol, Compliance Officer, U.S. Food and Drug Administration
E. Martell, Vice President, Quality Assurance and Regulatory Affairs, Theratronics

INSPECTION PROCEDURES USED

87103 Inspection of Incidents At Nuclear Materials Facilities

LIST OF ACRONYMS USED

CAL	Confirmatory Action Letter
CCTV	closed circuit television
FDA	U.S. Food and Drug Administration
RSO	radiation safety officer
SCR	silicon control rectifier
VALA	Veterans Administration Medical Center, West Los Angeles