POLICY AND PROCEDURE MANUAL
FOR
RADIATION ONCOLOGY
OZARKS MEDICAL CENTER
WEST PLAINS, MISSOURI

The following definitions, policies and procedures are established to provide high confidence that byproduct material or radiation from byproduct material is administered as directed by the authorized user in a safe and prudent manner.

DEFINITIONS: For <u>teletherapy procedures</u> the following definitions are given as contained in 10 CFR 35.2:

Misadministration means the administration of a teletherapy dose:
(1) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;
(2) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
(3) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
(4) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the prescribed dose.

Prescribed dose means the total dose and dose per fraction as documented in the written directive.

Written directive means an order in writing for a specific patient, dated and signed by the authorized user prior to the administration of radiation. This definition shall contain the total dose, the dose per fraction, the treatment site, and the overall treatment period (e.g., total number of treatments).

Recordable event means the administration of:
(1) Radiation without a written directive where a written directive is required;
(2) Radiation where a written directive is required without daily recording of each administered radiation dose in the appropriate record.
(3) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.

POLICIES and PROCEDURES:

Training Program.

1) Training will be provided:
   a) Before an employee assumes duties with or in the immediate vicinity of radioactive materials,
   b) Annually as refresher training for all employees, and
   c) Whenever a significant change occurs in duties, regulations, or the terms of the NRC license.

2) Description of the Training Program
   a) Individuals who work in or frequent restricted areas are instructed in the items specified in Section 19.12 of Title 10 Code of Federal Regulations, Part 19, and
   b) Individuals whose duties may require work in the immediate vicinity of radioactive materials are informed about radiation hazards and appropriate precautions.

3) The program of instruction will include:
   a) Pertinent terms and conditions of the NRC license, including procedures developed as a prerequisite for obtaining the license and commitments incorporated into the license by condition.
   b) Appropriate response to emergencies or unsafe conditions, including participation by appropriate staff in "dry runs" of emergency procedures conducted as a part of the initial and annual refresher training.
   c) Areas where radioactive material are used or stored.
   d) Potential hazards associated with radioactive material.
   e) Radiological safety procedures appropriate to the duties of the employee.
   f) Pertinent NRC regulations.
   g) The obligation of all personnel to report unsafe conditions to the radiation safety officer.
   h) The right of all personnel to be informed of radiation exposure and bioassay results.
   i) The locations where the licensee has posted or made available notices, copies of regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence) as required by 10 CFR Part 19.

4) Records of initial and refresher training will be maintained until the NRC terminates the teletherapy license and will include:
   a) The name of the individual who conducted the training,
   b) The names of the individuals who received the training,
   c) The dates and duration of the training session, and
   d) A list of the topics covered

General Operating Procedures

1) The teletherapy unit may only be operated to treat patients or irradiated blood by licensed physicians specifically approved by our NRC Teletherapy License or a qualified individual under the supervisionof an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist).

2) Each day the unit is used the Theratron 780 Daily Safety Check List must be performed before the unit is used to treat patients. This is a check of the units safety devices for proper operation. The date and results of all checks are to be logged in the proper log. Any malfunction or defects detected are to be reported immediately to the radiation oncologist and radiation safety officer and corrected promptly. A notation of the date on which each malfunction or defect was corrected must be maintained for at least two years after each check and each correction of a malfunction or defect.

3) Prior to administration of any teletherapy dose, verify that a written directive by a licensed user is in the patient's chart indicating that the radiation dose is to be administered. The written directive is an order for this specific patient and is to include the treatment site, the dose per fraction, the total dose, the overall treatment period (e.g., number of fractions), and the date and signature of an authorized user.

4) Prior to each administration of a teletherapy dose, the patient's identity is to be verified by more than one method as the individual named in the written directive. The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance, or the photograph of the patient's face.

5) The final plans of treatment and related calculations for the teletherapy dose are to be approved by an authorized user and are in accordance with the respective written directive.

6) Never turn the primary beam on with anyone but the patient in the treatment room. The operator shall ensure that no one but the patient being treated is in the room by being the last one (except patient) out of the room and closing the door behind them.

General Operating Procedures (cont).

7) Before administering each teletherapy dose, verify that the specific details of the administration are in accordance with the written directive and plan of treatment. In particular, the treatment site and the dose per fraction should be confirmed by the person administering the teletherapy treatment to be in accordance with the written directive.

8) If there is any question as to how to carry out the written directive, the treatment plan or how to set-up the patient, seek guidance from the authorized user. If there are any questions about what to do or how it should be done, ask and seek help. Do not continue any procedure when there is any doubt.

9) With the patient set-up, and everyone except the patient out of the room and the door closed, prepare the console for the desired treatment by:
   a) Set the desired type of treatment (i.e.,: Fix or Rotation)
   b) Set the desired treatment time.
   c) Press RESET and the reset button's light should go out. If the reset button's light does not clear: check if the treatment door is closed, check and see if the CONSOLE button on the hand control in the room is pushed, check and see if the OFF SHIELD light on the gantry head is off and make sure the digital timer has time set on it and the desired type of treatment is set.
   d) Assure yourself that the patient is still in position by observing the patient on the monitor before proceeding. If all is ok, press the TX button to turn on the primary beam to treat the patient.
   e) When the TX button is pushed the red BEAM ON light should light and the green BEAM OFF light should go out within a few seconds. If this does not happened, terminate the treatment at once by pushing any number on the digital timer and remove the patient. Do not push the emergency off on the console unless the unit is moving inappropriately as this sounds an alarm which might frighten the patient. Remove the patient from the treatment room and notify the radiation therapist and radiation safety officer of the malfunction at once.
   f) Always observe the patient in the monitor after positioning and during treatment. **Do not leave the console area during the treatment.**

General Operating Procedures (cont).

g) If the patient moves his/her treatment area in any manner while the beam is on, interrupt the treatment by pushing any number on the digital timer. Again, do not push the emergency off on the console unless the unit is moving inappropriately as the emergency off sounds an alarm which might frighten the patient. Enter the room and check the the set-up before continuing the treatment.

h) At the end of the set treatment time the source should return itself to the off position. The green BEAM OFF light should light and the red BEAM ON light should go out within a few seconds of termination of treatment. If this does not happened, terminate the treatment at once by pushing the emergency off immediately, check to see if the source has fully retracted and follow the posted emergency procedures if the source has not.

10) At the conclusion of each teletherapy dose fraction, make, date and initial a written record in the patient's treatment chart that contains the following for each treatment field: the total treatment time, the dose administered, and the cumulative dose administered. 10 CFR 35.32(d) requires that each written directive and a record of each administered radiation dose be retained for at least three years after administration.

11) If the equipment or beam fails in any manner, remove the patient first before calling service or doing anything else.

12) Do not treat any patients if the BEAM ON and the BEAM OFF indicators on the treatment console or those on the gantry or those above the treatment room door stay on simultaneously.

13) The beam can only be operated only while pointed at the integrated beam shield. The gantry is to be pointed toward the beam shield and the HEAD LOCK engaged (light on the gantry illuminated) when treating all patients.

14) Do not rotate the gantry to the 180° (PA) position with the HEAD LOCK off. The gantry can freeze into a fixed position and require service to release the safety interlock.

15) Do not rotate the gantry with custom block trays in place. There could be a risk of the tray falling out.

16) The four screws on the tray attachment and the two screws on the safety bar are to be tight before inserting a custom block tray.

General Operating Procedures (cont)

17) If the couch or gantry moves without your assistance, engage the emergency off if the patient is in danger and remove the patient immediately and have service correct before continuing to use the unit.

18) Move the couch out longitudinally slowly to the zero position. If you bring the couch out too fast, it can break the master link on the chain drive.

19) If the cobalt-60 light field should burn out, a field coincidence check is to be performed following the replacement of the bulb before treating any patient.

20) Report promptly to the radiation oncologist, the radiation safety officer, and the radiation physicist any unusual condition, malfunction or defect detected.

Oral Directives and Revisions to Written Directives

A footnote to 10 CFR 35.32(a)(1) reads as follows:

> "If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.
>
> "Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by the authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.
>
> "If, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive."

Chart and Dose Calculation Checks

1) The dose calculation is to be checked by comparing the manual calculation with the computer calculation or by someone who did not make the original calculation.
   (a) If the prescribed dose is to be administered in more than three fractions, this dose calculation check is to be made within three working days.
   (b) If the prescribed dose is to be administered in three fractions or less, the dose calculation is to be checked before administering the first teletherapy fractional dose.

   Manual dose calculations should be checked for:
   (1) Arithmetic errors,
   (2) Appropriate transfer of data from the written directive, plan of treatment, tables, and graphs.
   (3) Appropriate use of all pertinent data in the calculations.

   The computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient was used in the calculation. This includes a check of SSD, depth, field sizes, trays, wedges, and desired dose consistent with the written directive and plan of treatment.

2) If a patient's plan of treatment includes (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration or (2) the use of beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) that were not measured in the most recent full calibration measurement, arrangement are to be made with the radiation physicist to have physical measurements of the teletherapy output made under applicable conditions prior to administration of the first teletherapy dose.

3) A weekly chart check is to be performed by a qualified person (e.g., radiation oncologist physician, radiation therapy physicist, radiation therapy technologist, or dosimetrist,) to detect mistakes (such as arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative teletherapy dose administrations from all treatment fields, or in connection with any changes in any in the written directive or plan of treatment.

4) If during any check a recordable event or misadministration is discovered, notify the Radiation Safety Officer and the Radiation Physicist immediately so that appropriate action can be taken.

5) Acceptance testing by a qualified person (e.g., a radiation physicist shall be performed on each treatment planning or dose calculating computer program that could be used for teletherapy dose calculations before its first use for teletherapy dose calculations. Each treatment planning or dose calculating computer program is to be assessed based on the licensee's specific needs and applications.

Notifications, Reports and Records of Recordable Events

1) ***Recordable event*** means for teletherapy the administration of:
   (a) Radiation without a written directive where a written directive is required;
   (b) Radiation where a written directive is required without daily recording of each administered radiation dose in the appropriate record.
   (c) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.

2) Each recordable event shall be evaluated and a written response formed within 30 days after discovery of the recordable event by:
   (a) Assembling the relevant facts including the cause;
   (b) Identifying what, if any, corrective action is required to prevent recurrence; and
   (c) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

Notifications, Reports and Records of Misadministrations

1) *Misadministration* means for teletherapy the administration of a teletherapy dose:
   (a) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;
   (b) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
   (c) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
   (d) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the prescribed dose.

2) For a misadministration, the NRC Operations Center (phone number: (301) 816-5100) is to be notified by phone no later than the next calender day after discovery of the misadministration.

3) The referring physician and the patient are to be notified of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgement, telling the patient would be harmful. (The licensee is not required to notify the patient without first consulting the referring physician). If the referring physician or patient cannot be reached within 24 hours, the patient is to be notified as soon as possible thereafter. Any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, is not to be delayed because of any delay in notification.

4) If the patient was notified, then a written report shall also be furnished, within 15 days after discovery of the misadministration, by sending either:
   (a) A copy of the report submitted to the NRC; or
   (b) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

5) A written report is to be submitted to the appropriate NRC Regional Office within 15 days after discovery of the misadministration. The written report must include:
   (a) The licensee's name;
   (b) The prescribing physician's name;
   (c) A brief description of the event;
   (d) Why the event occurred;
   (e) The effect on the patient;

Notifications, Reports and Records of Misadministrations (cont.)

(f) What improvements are needed to prevent recurrence;
(g) Actions taken to prevent recurrence;
(h) Whether the licensee notified the patient, or the patient's responsible relative or guardian, and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name, or the patient's responsible relative or guardian, or other information that could lead to identification of the patient.

6) A record of each misadministration shall be maintained for five years. The record must contain the following:
   (a) The names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician);
   (b) The patient's social security number or identification number if one has been assigned;
   (c) A brief description of the misadministration;
   (d) Why it occurred;
   (e) The effect on the patient;
   (f) What improvements are needed to prevent recurrence; and
   (g) The actions taken to prevent recurrence.

7) Aside from the notification requirement, these procedures are to have no affect on any rights or duties of licensees and physicians in relation to each other, patients or the patient's responsible relatives or guardians.

Quality Management Periodic Review Program

1) A review of the quality management program shall be conducted at intervals no greater than 12 months to verify compliance with all aspects of the quality management program. This review shall include, since the last review, an evaluation of:
   (a) All administrations where the written directive was completed during the review period,
   (b) Any administrations in charts that were not available during the last review,
   (c) All recordable events, and
   (d) All misadministrations.

2) Each review is to be evaluated to determine the effectiveness of the quality management program and, if required, make modifications to the program to provide high confidence that radiation will be administered as directed by the authorized user.

3) Records of each review, including the evaluation and findings of the review are to be retained in an auditable form for three years.

4) For each patient's case, a comparison should be made between what was administered versus what was prescribed in the written directive or plan of treatment. For teletherapy this includes verifying agreement of total dose, dose per fraction, treatment site, and overall treatment period. If the difference between what was administered and what was prescribed exceeds the criteria for either a recordable event or a misadministration, the comparison is unacceptable.

5) For each deviation from the written directive found during review, the cause should be identified and action taken to prevent recurrence. The actions taken may include new or revised policies, new or revised procedures, additional training, or increased supervisory review of work. Corrective actions for deficient conditions should be implemented within a reasonable time after identification of the deficiency.

6) The quality management program may be modified to increase the program's efficiency provided the program's effectiveness is not decreased. All modifications are to be sent to the appropriate NRC Regional Office within 30 days after the modification has been made.

Theratron 780 Daily Safety Check List Instructions

1) Turn on the television monitor and intercom. Insert key into the Cobalt-60 unit console and turn all the way to the right to the reset position, then quickly release. When you turn the key, an alarm sounds which will stop when you release the key after turning it to the reset position.

2) Check the timer and make sure it is illuminated.

3) CONSOLE EMERGENCY OFF: Push the large red EMERGENCY OFF button on the console and release. When you push the emergency off button, an alarm sounds which will stop when you reset with the console key. To reset, turn the console key to the right to the reset position and quickly release.

4) WALL MONITOR (RADIATION SENSOR-PRIMALERT): Place the cesium check source on top of the Primalert room monitor with the label down. The Primalert large red button should start to flash within a few seconds, then remove the cesium check source and put it back. Make sure the Primalert red button stops flashing when the source is removed. If the radiation room monitor is inoperable for any reason, any person entering the treatment room shall use a properly operating portable survey instrument.

5) HAND CONTROL CONSOLE BUTTON: Press any button on the hand control in the treatment room except the CONSOLE button. Make sure the treatment room door is closed and no one in the room. Set 1.00 on the digital timer. Push white FIX button. Push yellow RESET button. The yellow RESET button should stay lit if the hand control CONSOLE button is not depressed.

6) HAND CONTROL EMERGENCY OFF: Open the treatment room door and enter the Cobalt room. Depress the EMERGENCY OFF on the hand control. An alarm will sound when you push the hand control emergency off and will stop when the unit is reset. The unit can be reset by pushing the black reset button on the left side of the treatment unit or by using the reset key on the control console.

7) TREATMENT MACHINE EMERGENCY OFF: Push the large red EMERGENCY OFF button on the side of the cobalt unit. An alarm will sound. The button will stay depressed. Twist the button to release. Push the black restart button on the left side of the treatment unit and the alarm will stop.

Theratron 780 Daily Safety Check List Instructions (cont.)

8) CONSOLE, DOOR AND GANTRY BEAM ON/BEAM OFF INDICATORS AND TREATMENT INTERRUPTION: Press the CONSOLE button on the hand control and exit the treatment room. Making sure no one else is in the treatment room, close the treatment room door. Set 1.00 on the digital timer. Press FIX. Press RESET. Press the TX button on the digital timer. Check and see if the red BEAM ON lights are illuminated on the Cobalt-60 console, above the treatment room door and by looking on the monitor, on the Cobalt-60 gantry head. Push any number on the digital timer to INTERRUPT the simulated treatment while watching the BEAM OFF light to illuminate on the television monitor. Check the BEAM OFF light above the treatment room door and the BEAM OFF light on the Cobalt-60 console.

9) DOOR SAFETY OFF (SAFETY INTERLOCK): Set 1.00 on the digital timer. Push FIX. Push RESET. Push TX on the digital timer. Push the treatment room door open quickly and note whether the Cobalt-60 unit automatically shuts off.

10) TIMER: Set 1.00 on the digital timer. Push FIX. Push RESET. Push TX. Check the timer against a second hand on a watch or clock.

11) Note the results of all checks in the proper daily log. Report promptly to the radiation oncologist and the radiation safety officer any unusual condition, malfunction or defect detected.

Personnel Dosimetry.

1) Whole-body film badges will be provided to all personnel who work in the radiation center and may enter restricted areas.

2) The whole-body film badges are exchanged for processing at intervals not to exceed one month.

3) The whole-body film badges will be provided by and processed by a commercial personnel dosimetry service company.

4) Any pocket dosimeters that are used to make exposures from licensed material will be operable, calibrated, and tested for drift at intervals not to exceed one year.

5) In the event that a person receives or suspects that he/she has received a high exposure, the film badge of the affected person is to be processed immediately and the person removed from restricted areas until the results are known.

Procedures for Securing the Teletherapy Unit.

The following actions are to be performed to secure the teletherapy unit from unauthorized use.

1) The treatment room door is to be kept closed and locked when the teletherapy unit is not being used.

2) Anytime the department is to be left unattended, the treatment room door and the control console are to be locked and the keys secured from unauthorized use.

Instrument Calibration and Checks

1) Survey instruments will be returned to the manufacturer for calibration or calibrated by Radiation Consultants of Mid-America, 5500 Buena Vista, Shawnee Mission, Kansas 66205.

2) Survey instruments are to be calibrated at intervals not to exceed one year and after repair.

3) Records of each calibration are to be maintained for at least two years after calibration. These records will show the date and results of the calibration and the name of the organization that provided the service.

4) The beam-on room monitor is to be checked daily for proper operation using the instructions in the Theratron 780 Daily Check List Instructions. If the radiation monitor is inoperable for any reason, any person entering the teletherapy room shall use a properly operating portable survey instrument.

5) The survey instrument is to be tested each day it is used before use.

6) Full calibration measurements shall be performed yearly using a dosimetry system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.

7) Monthly spot-check measurements shall be performed using a dosimetry system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicist in Medicine within the previous two years or after any servicing or by a dosimetry system that has been calibrated by direct intercomparison within the previous one year with a system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicist in Medicine.

Full Calibration of the Teletherapy Unit

1) The teletherapy unit shall have full calibration measurement when:
   a) Prior to the first use of the unit for treating humans
   b) Prior to treating humans :
      (1) Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for physical decay;
      (2) Following replacement of the radiation source or following reinstatement of the teletherapy unit in a new location;
      (3) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components of the source exposure assembly; and
   b) At intervals not to exceeding one year.

2) Full calibration measurements shall include determination of:
   a) The dose rate to an accuracy within ±3 percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;
   b) The congruence between the radiation field and the field indicated by the light beam localizing device.
   c) The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
   d) Timer accuracy;
   e) The accuracy of all distance measuring devices used for treating humans; and
   f) The determination of transmission factors for wedges and trays.

3) Full calibration measurements shall be made in accordance with procedures and recommendations by Task Group 21 of the American Association of Physicists in Medicine (*Medical Physics*, December, 1983).

4) The dose rate values shall be corrected mathematically for physical decay for intervals not exceeding one month.

5) Full calibration measurements shall be performed yearly using a dosimetry system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.

Full Calibration of the Teletherapy Unit (cont.)

6) Full calibration measurements and the physical decay corrections shall be performed by Dennis Frieda, Ph.D. or an equivalent expert qualified by training and experience to calibrate a teletherapy unit. The licensee shall determine that the qualified expert:
   a) Is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics.; or
   b) Has the following minimum training and experience:
      1) A Master's or Doctor's degree in physics, biophysics, radiological physics, medical physics or health physics;
      2) One year of full time training in therapeutic radiological physics; and
      3) One year of full time experience in a radiotherapy facility including personal calibration and spot check of at least one teletherapy unit.

7) After full calibrations measurements that resulted from replacement of the source, or from a spot-check that indicated that the output differed by more than 5 percent from the output obtained at the last full calibration corrected for radioactive decay, an independent check of the output for a single specified set of exposure conditions should be performed. this independent check should be performed within 30 days following such full calibration measurements.
   The independent check will be performed by either:
   (1) A qualified individual who did not perform the full calibration using a dosimetry system other than the one that was used during the full calibration. The dosimetry shall have been calibrated within the previous two years and after any servicing that may have affected system calibration; or
   (2) A teletherapy physicist (or an oncology physician, dosimetrist, or radiation therapy technologist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming teletherapy doses and that is accurate within 5 percent.

Monthly Spot-Check of the Teletherapy Unit

1) Spot-check measurements shall be performed on a monthly basis.

2) Spot-check measurements shall include determination of:
   a) Timer accuracy;
   b) The congruence of the radiation field and the field indicated by the light beam localizing device;
   c) The accuracy of all distance measuring devices used for treating humans;
   d) The dose rate for one typical set of operating conditions; and
   e) The difference between this measurement and the anticipated output, expressed as a percentage of the anticipated output.

3) Spot-check measurements shall be performed by Dennis Frieda, Ph.D. or an equivalently qualified expert.

4) The spot-check measurements shall be performed using a dosimetry system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicist in Medicine within the previous two years or after any servicing or by a dosimetry system that has been calibrated by direct intercomparison within the previous one year with a system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicist in Medicine.

Leak Test Procedures.

1) The teletherapy source shall be tested for leakage at intervals not to exceed six months.

2) A Sealed Source Leak Test Kit obtained from Monitoring Services, Houston, Texas, will be used for taking the test sample. Their instruction for using the kit will be followed.

3) Source smears or wipes will be obtained by Dennis Frieda, Ph.D., Radiological Physicist, and taken from locations where contamination, if present, is likely to accumulate. This includes, but is not limited to, the inner surface of the beam collimating device, and the area near where the source is located when the source is in the "ON" position.

4) All test samples will be obtained with the source in the "OFF" position. Test samples will be taken with adequate precautions to minimize radiation exposure and spread of contamination.

5) Test samples will be returned to Monitoring Services, Houston, Texas, for counting and evaluation. Before mailing, all test samples will be monitored with a portable low-range survey meter or radiation monitor. If levels are in excess of twice background, the source will assume to be leaking and the licensee shall promptly take appropriate action to prevent the spread of contamination.

6) Records of each leak test will be maintained for at least two years.

Inspections and Servicing of the Teletherapy Unit

1) The teletherapy unit is to be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

2) This five year inspection and servicing of the teletherapy unit shall be performed by persons specifically licensed to do so by the Commission.

Limitations on Work Done on Teletherapy Unit

Only persons or firms specifically authorized by the NRC are to perform the following services:

1) Install, relocate , or remove teletherapy units containing sources;

2) Perform source exchanges;

3) Perform any maintenance or repair on teletherapy unit that involves the source drawer, the shutter, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

Relocation of the Teletherapy Unit.

The NRC must approve any plans and the proposed location before the teletherapy unit is relocated or moved from its present location.

Radiation Survey Reports

1) Radiation survey reports shall be performed following each installation of a teletherapy source and prior to initiation of a treatment program.

2) A radiation survey shall contain, as a minimum, the information identified in Appendix F of Draft Regulatory Guide FC 414-4, dated December 1985.

3) Survey measurements shall be performed by Dennis Frieda, Ph.D. or an equivalent expert qualified by training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise on protection needs and who has good knowledge and understanding of the operating characteristics, including the limitations, of the radiation detection instrumentations and measuring devices that are used in the survey. The licensee shall determine that the qualified expert:
   a) Is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or
   b) Has the following minimum training and experience:
      (1) A Master's or Doctor's degree in physics, biophysics, radiological physics, medical physics or health physics;
      (2) One year of full time training in therapeutic radiological physics; and
      (3) One year of full time experience in a radiotherapy facility including personal calibration and spot check of at least one teletherapy unit.

4) A report of the survey results and tests shall be sent to the U.S. Nuclear Regulatory Commission, Region III, Materials Licensing Section, 801 Warrenville Road, Lisle, Illinois 60532-4351, not more than 30 days after each installation of a teletherapy source.

Recordkeeping

1) The following records are to be maintained until the NRC authorizes their disposition:
   a) Personnel dosimetry records.

2) The following records are to be maintained until the NRC terminates the teletherapy license:
   a) Copies of NRC licenses, our license applications, and correspondence with the NRC in support of the license request.
   b) Records of daily checks of room beam-on monitor.
   c) Records of training of new personnel and annual refresher training of personnel.

3) The following records are to be maintained for five years after said action was performed:
   a) A record of each misadministration.
   b) Results of full calibration measurements.
   c) Records of the calibration of the dosimetry system used for full calibration measurements.
   d) Records of the licensee's evaluation of the qualified expert's training and experience.
   e) Copies of reports of surveys conducted in accordance with any installation of a teletherapy source.
   f) Records of the transfer of radioactive material.

4) The following records are to be maintained in an auditable form for three years:
   a) Records of each quality management review, including the evaluations and findings of the review.
   b) A record of the relevant facts and what corrective action, if any, was taken for each recordable event.
   c) Each written directive and the record of each administered radiation dose where a written directive was required.

5) The following records are to be maintained for two years after completion of said action:
   a) Records of results of daily safety device checks.
   b) Results of spot-check measurements.
   c) Records of the calibration or intercomparison of the dosimetry system used for spot-check measurements.
   d) Records of leak-test results.
   e) Records of survey instrument calibrations.
   f) Records of receipt of radioactive material are to be maintained for two years following transfer, or disposal of the radioactive material.

Emergency Procedures

1) All new teletherapy personnel are required to be trained in emergency procedures as soon as they report for duty.

2) Practice drills in emergency procedures are to be conducted with all appropriate personnel at least once a year.

3) The following emergency procedures are to be posted at the teletherapy unit console, and followed when necessary.

EMERGENCY PROCEDURES FOR BEAM CONTROL FAILURE OR MALFUNCTION

If the light signals or the beam-on monitor indicates that the beam control mechanism has failed to terminate the exposure at the end of the preset time (e.g., if the red light stays on and the green light is off, or if both the red and the green lights stay on for more than a few seconds) the source may still be in the "on" position. The following steps are to carried out promptly and in a calm manner by the Radiation Therapy Technologist.

1) Open the door to the treatment room.
2) If the patient is ambulatory, tell him or her to get off the table and leave the room.
3) If the patient is not ambulatory, enter the treatment room but avoid exposure to the direct beam. Pull the treatment table as far away from the direct beam as possible. Transfer the patient to a stretcher and remove the patient from the room.
4) Close the door and secure the area by locking the door to the treatment room or posting a guard at the entrance.
5) Turn off the main switch at the control panel.
6) Notify the radiation therapist, radiation safety officer and radiation physicist at once.
7) Conspicuously post a sign in the area to warn others of the problem.

Radiation Therapist and Radiation Safety Officer: Liep Tio, M.D.
Phone No.: On Duty: 257-7082 Off Duty: 257-7408

Radiation Physicist: Dennis Frieda, Ph.D.
Phone No.: On Duty: 1-882-9960 Off Duty: 1-882-7416

Procedures for Notifying the Proper Persons in the Event of an Accident or Unusual Occurrence.

1) Report promptly to the radiation oncologist, the radiation safety officer, and the radiation physicist any unusual condition, malfunction or defect detected while using the teletherapy unit at any time.

2) The NRC Operations Center is to be notified as soon as possible but no later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposure to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

3) Theratronics (AECL) is to be contacted to perform any of the following services:
   a) Perform any maintenance or repair on teletherapy unit that involves the source drawer, the shutter, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels;
   b) Perform source exchanges; and
   c) Install, relocate, or remove teletherapy units containing sources.

4) The NRC Operations Center is to be notified by telephone within 24 hours after discovery of any of the following events involving licensed material:
   a) An unplanned contamination event that:
      (1) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
      (2) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of 20.1001-20.2401 of 10 CFR part 20 for the material;
      (3) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
   b) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
   c) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
      (1) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of 20.1011-20.2401 of 10 CFR part 20; and

Procedures for Notifying the Proper Persons in the Event of an Accident or Unusual Occurrence (cont.).

(2) The damage affects the integrity of the licensed material or its container.

d) Any misadministration.

5) The following reports must be made for any teletherapy misadministration.

a) Within 24 hours after discovering the misadministration, the licensee shall notified:

(1) The administrator of the hospital;
(2) The NRC Operations Center (phone #: (301) 951-0550);
(3) The referring physician of the affected patient; and
(4) The patient or a responsible relative (or guardian), unless the referring physician personally informs the licensee either that he will inform the patient or that, in his medical judgment, telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other. The licensee is not required to notify the patient without first consulting the referring physician.

b) Within 15 days after the initial therapy misadministration report to the NRC, a written report will be sent to:

(1) The NRC Regional Office;
(2) The patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee.

6) The following are the names and phone numbers of the appropriate people or organizations to contact:

a) Radiation Oncologist and Radiation Safety Officer: Liep Tio, M.D.
Phone No.: On Duty: 257-7082 Off Duty: 257-7408

b) Radiation Physicist: Dennis Frieda, Ph.D.
Phone No.: On Duty: 1-882-9960 Off Duty: 1-882-7416

c) Administration: Charles R. Brackney
Phone No.: On Duty: 257-6700

d) Theratronics (AECL) for service:
Phone No.: Dallas Regional Office: (214) 233-0939
Chicago Regional Office: (312) 593-3242

e) U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road, Lisle, IL
Phone No.: (708) 829-9500

f) U.S. Nuclear Regulatory Operation Center
Phone No.: (301) 816-5100

POLICY AND PROCEDURE MANUAL
FOR
RADIATION ONCOLOGY
OZARKS MEDICAL CENTER
WEST PLAINS, MISSOURI

The following definitions, policies and procedures are established to provide high confidence that byproduct material or radiation from byproduct material is administered as directed by the authorized user in a safe and prudent manner.

DEFINITIONS: For teletherapy procedures the following definitions are given as contained in 10 CFR 35.2:

Misadministration means the administration of a teletherapy dose:
(1) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;
(2) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
(3) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
(4) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the prescribed dose.

Prescribed dose means the total dose and dose per fraction as documented in the written directive.

Written directive means an order in writing for a specific patient, dated and signed by the authorized user prior to the administration of radiation. This definition shall contain the total dose, the dose per fraction, the treatment site, and the overall treatment period (e.g., total number of treatments).

Recordable event means the administration of:
(1) Radiation without a written directive where a written directive is required;
(2) Radiation where a written directive is required without daily recording of each administered radiation dose in the appropriate record.
(3) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.

POLICIES and PROCEDURES:

Training Program.

1) Training will be provided:
   a) Before an employee assumes duties with or in the immediate vicinity of radioactive materials,
   b) Annually as refresher training for all employees, and
   c) Whenever a significant change occurs in duties, regulations, or the terms of the NRC license.

2) Description of the Training Program
   a) Individuals who work in or frequent restricted areas are instructed in the items specified in Section 19.12 of Title 10 Code of Federal Regulations, Part 19, and
   b) Individuals whose duties may require work in the immediate vicinity of radioactive materials are informed about radiation hazards and appropriate precautions.

3) The program of instruction will include:
   a) Pertinent terms and conditions of the NRC license, including procedures developed as a prerequisite for obtaining the license and commitments incorporated into the license by condition.
   b) Appropriate response to emergencies or unsafe conditions, including participation by appropriate staff in "dry runs" of emergency procedures conducted as a part of the initial and annual refresher training.
   c) Areas where radioactive material are used or stored.
   d) Potential hazards associated with radioactive material.
   e) Radiological safety procedures appropriate to the duties of the employee.
   f) Pertinent NRC regulations.
   g) The obligation of all personnel to report unsafe conditions to the radiation safety officer.
   h) The right of all personnel to be informed of radiation exposure and bioassay results.
   i) The locations where the licensee has posted or made available notices, copies of regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence) as required by 10 CFR Part 19.

4) Records of initial and refresher training will be maintained until the NRC terminates the teletherapy license and will include:
   a) The name of the individual who conducted the training,
   b) The names of the individuals who received the training,
   c) The dates and duration of the training session, and
   d) A list of the topics covered

General Operating Procedures

1) The teletherapy unit may only be operated to treat patients or irradiated blood by licensed physicians specifically approved by our NRC Teletherapy License or a qualified individual under the supervisionof an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist).

2) Each day the unit is used the Theratron 780 Daily Safety Check List must be performed before the unit is used to treat patients. This is a check of the units safety devices for proper operation. The date and results of all checks are to be logged in the proper log. Any malfunction or defects detected are to be reported immediately to the radiation oncologist and radiation safety officer and corrected promptly. A notation of the date on which each malfunction or defect was corrected must be maintained for at least two years after each check and each correction of a malfunction or defect.

3) Prior to administration of any teletherapy dose, verify that a written directive by a licensed user is in the patient's chart indicating that the radiation dose is to be administered. The written directive is an order for this specific patient and is to include the treatment site, the dose per fraction, the total dose, the overall treatment period (e.g., number of fractions), and the date and signature of an authorized user.

4) Prior to each administration of a teletherapy dose, the patient's identity is to be verified by more than one method as the individual named in the written directive. The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance, or the photograph of the patient's face.

5) The final plans of treatment and related calculations for the teletherapy dose are to be approved by an authorized user and are in accordance with the respective written directive.

6) Never turn the primary beam on with anyone but the patient in the treatment room. The operator shall ensure that no one but the patient being treated is in the room by being the last one (except patient) out of the room and closing the door behind them.

General Operating Procedures (cont)

7) Before administering each teletherapy dose, verify that the specific details of the administration are in accordance with the written directive and plan of treatment. In particular, the treatment site and the dose per fraction should be confirmed by the person administering the teletherapy treatment to be in accordance with the written directive.

8) If there is any question as to how to carry out the written directive, the treatment plan or how to set-up the patient, seek guidance from the authorized user. If there are any questions about what to do or how it should be done, ask and seek help. Do not continue any procedure when there is any doubt.

9) With the patient set-up, and everyone except the patient out of the room and the door closed, prepare the console for the desired treatment by:
   a) Set the desired type of treatment (i.e.,: Fix or Rotation)
   b) Set the desired treatment time.
   c) Press RESET and the reset button's light should go out. If the reset button's light does not clear: check if the treatment door is closed, check and see if the CONSOLE button on the hand control in the room is pushed, check and see if the OFF SHIELD light on the gantry head is off and make sure the digital timer has time set on it and the desired type of treatment is set.
   d) Assure yourself that the patient is still in position by observing the patient on the monitor before proceeding. If all is ok, press the TX button to turn on the primary beam to treat the patient.
   e) When the TX button is pushed the red BEAM ON light should light and the green BEAM OFF light should go out within a few seconds. If this does not happened, terminate the treatment at once by pushing any number on the digital timer and remove the patient. Do not push the emergency off on the console unless the unit is moving inappropriately as this sounds an alarm which might frighten the patient. Remove the patient from the treatment room and notify the radiation therapist and radiation safety officer of the malfunction at once.
   f) Always observe the patient in the monitor after positioning and during treatment. **Do not leave the console area during the treatment.**

General Operating Procedures (cont)

g) If the patient moves his/her treatment area in any manner while the beam is on, interrupt the treatment by pushing any number on the digital timer. Again, do not push the emergency off on the console unless the unit is moving inappropriately as the emergency off sounds an alarm which might frighten the patient. Enter the room and check the the set-up before continuing the treatment.

h) At the end of the set treatment time the source should return itself to the off position. The green BEAM OFF light should light and the red BEAM ON light should go out within a few seconds of termination of treatment. If this does not happened, terminate the treatment at once by pushing the emergency off immediately, check to see if the source has fully retracted and follow the posted emergency procedures if the source has not.

10) At the conclusion of each teletherapy dose fraction, make, date and initial a written record in the patient's treatment chart that contains the following for each treatment field: the total treatment time, the dose administered, and the cumulative dose administered. 10 CFR 35.32(d) requires that each written directive and a record of each administered radiation dose be retained for at least three years after administration.

11) If the equipment or beam fails in any manner, remove the patient first before calling service or doing anything else.

12) Do not treat any patients if the BEAM ON and the BEAM OFF indicators on the treatment console or those on the gantry or those above the treatment room door stay on simultaneously.

13) The beam can only be operated only while pointed at the integrated beam shield. The gantry is to be pointed toward the beam shield and the HEAD LOCK engaged (light on the gantry illuminated) when treating all patients.

14) Do not rotate the gantry to the 180° (PA) position with the HEAD LOCK off. The gantry can freeze into a fixed position and require service to release the safety interlock.

15) Do not rotate the gantry with custom block trays in place. There could be a risk of the tray falling out.

16) The four screws on the tray attachment and the two screws on the safety bar are to be tight before inserting a custom block tray.

General Operating Procedures (cont).

17) If the couch or gantry moves without your assistance, engage the emergency off if the patient is in danger and remove the patient immediately and have service correct before continuing to use the unit.

18) Move the couch out longitudinally slowly to the zero position. If you bring the couch out too fast, it can break the master link on the chain drive.

19) If the cobalt-60 light field should burn out, a field coincidence check is to be performed following the replacement of the bulb before treating any patient.

20) Report promptly to the radiation oncologist, the radiation safety officer, and the radiation physicist any unusual condition, malfunction or defect detected.

Oral Directives and Revisions to Written Directives

A footnote to 10 CFR 35.32(a)(1) reads as follows:

"If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.

"Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by the authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

"If, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive."

Chart and Dose Calculation Checks

1) The dose calculation is to be checked by comparing the manual calculation with the computer calculation or by someone who did not make the original calculation.
   (a) If the prescribed dose is to be administered in more than three fractions, this dose calculation check is to be made within three working days.
   (b) If the prescribed dose is to be administered in three fractions or less, the dose calculation is to be checked before administering the first teletherapy fractional dose.

   Manual dose calculations should be checked for:
   (1) Arithmetic errors,
   (2) Appropriate transfer of data from the written directive, plan of treatment, tables, and graphs.
   (3) Appropriate use of all pertinent data in the calculations.

   The computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient was used in the calculation. This includes a check of SSD, depth, field sizes, trays, wedges, and desired dose consistent with the written directive and plan of treatment.

2) If a patient's plan of treatment includes (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration or (2) the use of beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) that were not measured in the most recent full calibration measurement, arrangement are to be made with the radiation physicist to have physical measurements of the teletherapy output made under applicable conditions prior to administration of the first teletherapy dose.

3) A weekly chart check is to be performed by a qualified person (e.g., radiation oncologist physician, radiation therapy physicist, radiation therapy technologist, or dosimetrist,) to detect mistakes (such as arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative teletherapy dose administrations from all treatment fields, or in connection with any changes in any in the written directive or plan of treatment.

4) If during any check a recordable event or misadministration is discovered, notify the Radiation Safety Officer and the Radiation Physicist immediately so that appropriate action can be taken.

5) Acceptance testing by a qualified person (e.g., a radiation physicist shall be performed on each treatment planning or dose calculating computer program that could be used for teletherapy dose calculations before its first use for teletherapy dose calculations. Each treatment planning or dose calculating computer program is to be assessed based on the licensee's specific needs and applications.

Notifications, Reports and Records of Recordable Events

1) ***Recordable event*** means for teletherapy the administration of:
   (a) Radiation without a written directive where a written directive is required;
   (b) Radiation where a written directive is required without daily recording of each administered radiation dose in the appropriate record.
   (c) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.

2) Each recordable event shall be evaluated and a written response formed within 30 days after discovery of the recordable event by:
   (a) Assembling the relevant facts including the cause;
   (b) Identifying what, if any, corrective action is required to prevent recurrence; and
   (c) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

Notifications, Reports and Records of Misadministrations

1) ***Misadministration*** means for teletherapy the administration of a teletherapy dose:
   (a) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;
   (b) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
   (c) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
   (d) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the prescribed dose.

2) For a misadministration, the NRC Operations Center (phone number: (301) 816-5100) is to be notified by phone no later than the next calender day after discovery of the misadministration.

3) The referring physician and the patient are to be notified of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgement, telling the patient would be harmful. (The licensee is not required to notify the patient without first consulting the referring physician). If the referring physician or patient cannot be reached within 24 hours, the patient is to be notified as soon as possible thereafter. Any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, is not to be delayed because of any delay in notification.

4) If the patient was notified, then a written report shall also be furnished, within 15 days after discovery of the misadministration, by sending either:
   (a) A copy of the report submitted to the NRC; or
   (b) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

5) A written report is to be submitted to the appropriate NRC Regional Office within 15 days after discovery of the misadministration. The written report must include:
   (a) The licensee's name;
   (b) The prescribing physician's name;
   (c) A brief description of the event;
   (d) Why the event occurred;
   (e) The effect on the patient;

Notifications, Reports and Records of Misadministrations (cont.)

(f) What improvements are needed to prevent recurrence;
(g) Actions taken to prevent recurrence;
(h) Whether the licensee notified the patient, or the patient's responsible relative or guardian, and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name, or the patient's responsible relative or guardian, or other information that could lead to identification of the patient.

6) A record of each misadministration shall be maintained for five years. The record must contain the following:
   (a) The names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician);
   (b) The patient's social security number or identification number if one has been assigned;
   (c) A brief description of the misadministration;
   (d) Why it occurred;
   (e) The effect on the patient;
   (f) What improvements are needed to prevent recurrence; and
   (g) The actions taken to prevent recurrence.

7) Aside from the notification requirement, these procedures are to have no affect on any rights or duties of licensees and physicians in relation to each other, patients or the patient's responsible relatives or guardians.

Quality Management Periodic Review Program

1) A review of the quality management program shall be conducted at intervals no greater than 12 months to verify compliance with all aspects of the quality management program. This review shall include, since the last review, an evaluation of:
   (a) All administrations where the written directive was completed during the review period,
   (b) Any administrations in charts that were not available during the last review,
   (c) All recordable events, and
   (d) All misadministrations.

2) Each review is to be evaluated to determine the effectiveness of the quality management program and, if required, make modifications to the program to provide high confidence that radiation will be administered as directed by the authorized user.

3) Records of each review, including the evaluation and findings of the review are to be retained in an auditable form for three years.

4) For each patient's case, a comparison should be made between what was administered versus what was prescribed in the written directive or plan of treatment. For teletherapy this includes verifying agreement of total dose, dose per fraction, treatment site, and overall treatment period. If the difference between what was administered and what was prescribed exceeds the criteria for either a recordable event or a misadministration, the comparison is unacceptable.

5) For each deviation from the written directive found during review, the cause should be identified and action taken to prevent recurrence. The actions taken may include new or revised policies, new or revised procedures, additional training, or increased supervisory review of work. Corrective actions for deficient conditions should be implemented within a reasonable time after identification of the deficiency.

6) The quality management program may be modified to increase the program's efficiency provided the program's effectiveness is not decreased. All modifications are to be sent to the appropriate NRC Regional Office within 30 days after the modification has been made.

Theratron 780 Daily Safety Check List Instructions

1) Turn on the television monitor and intercom. Insert key into the Cobalt-60 unit console and turn all the way to the right to the reset position, then quickly release. When you turn the key, an alarm sounds which will stop when you release the key after turning it to the reset position.

2) Check the timer and make sure it is illuminated.

3) CONSOLE EMERGENCY OFF: Push the large red EMERGENCY OFF button on the console and release. When you push the emergency off button, an alarm sounds which will stop when you reset with the console key. To reset, turn the console key to the right to the reset position and quickly release.

4) WALL MONITOR (RADIATION SENSOR-PRIMALERT): Place the cesium check source on top of the Primalert room monitor with the label down. The Primalert large red button should start to flash within a few seconds, then remove the cesium check source and put it back. Make sure the Primalert red button stops flashing when the source is removed. If the radiation room monitor is inoperable for any reason, any person entering the treatment room shall use a properly operating portable survey instrument.

5) HAND CONTROL CONSOLE BUTTON: Press any button on the hand control in the treatment room except the CONSOLE button. Make sure the treatment room door is closed and no one in the room. Set 1.00 on the digital timer. Push white FIX button. Push yellow RESET button. The yellow RESET button should stay lit if the hand control CONSOLE button is not depressed.

6) HAND CONTROL EMERGENCY OFF: Open the treatment room door and enter the Cobalt room. Depress the EMERGENCY OFF on the hand control. An alarm will sound when you push the hand control emergency off and will stop when the unit is reset. The unit can be reset by pushing the black reset button on the left side of the treatment unit or by using the reset key on the control console.

7) TREATMENT MACHINE EMERGENCY OFF: Push the large red EMERGENCY OFF button on the side of the cobalt unit. An alarm will sound. The button will stay depressed. Twist the button to release. Push the black restart button on the left side of the treatment unit and the alarm will stop.

Theratron 780 Daily Safety Check List Instructions (cont.)

8) CONSOLE, DOOR AND GANTRY BEAM ON/BEAM OFF INDICATORS AND TREATMENT INTERRUPTION: Press the CONSOLE button on the hand control and exit the treatment room. Making sure no one else is in the treatment room, close the treatment room door. Set 1.00 on the digital timer. Press FIX. Press RESET. Press the TX button on the digital timer. Check and see if the red BEAM ON lights are illuminated on the Cobalt-60 console, above the treatment room door and by looking on the monitor, on the Cobalt-60 gantry head. Push any number on the digital timer to INTERRUPT the simulated treatment while watching the BEAM OFF light to illuminate on the television monitor. Check the BEAM OFF light above the treatment room door and the BEAM OFF light on the Cobalt-60 console.

9) DOOR SAFETY OFF (SAFETY INTERLOCK): Set 1.00 on the digital timer. Push FIX. Push RESET. Push TX on the digital timer. Push the treatment room door open quickly and note whether the Cobalt-60 unit automatically shuts off.

10) TIMER: Set 1.00 on the digital timer. Push FIX. Push RESET. Push TX. Check the timer against a second hand on a watch or clock.

11) Note the results of all checks in the proper daily log. Report promptly to the radiation oncologist and the radiation safety officer any unusual condition, malfunction or defect detected.

Personnel Dosimetry.

1) Whole-body film badges will be provided to all personnel who work in the radiation center and may enter restricted areas.

2) The whole-body film badges are exchanged for processing at intervals not to exceed one month.

3) The whole-body film badges will be provided by and processed by a commercial personnel dosimetry service company.

4) Any pocket dosimeters that are used to make exposures from licensed material will be operable, calibrated, and tested for drift at intervals not to exceed one year.

5) In the event that a person receives or suspects that he/she has received a high exposure, the film badge of the affected person is to be processed immediately and the person removed from restricted areas until the results are known.

Procedures for Securing the Teletherapy Unit.

The following actions are to be performed to secure the teletherapy unit from unauthorized use.

1) The treatment room door is to be kept closed and locked when the teletherapy unit is not being used.

2) Anytime the department is to be left unattended, the treatment room door and the control console are to be locked and the keys secured from unauthorized use.

Instrument Calibration and Checks

1) Survey instruments will be returned to the manufacturer for calibration or calibrated by Radiation Consultants of Mid-America, 5500 Buena Vista, Shawnee Mission, Kansas 66205.

2) Survey instruments are to be calibrated at intervals not to exceed one year and after repair.

3) Records of each calibration are to be maintained for at least two years after calibration. These records will show the date and results of the calibration and the name of the organization that provided the service.

4) The beam-on room monitor is to be checked daily for proper operation using the instructions in the Theratron 780 Daily Check List Instructions. If the radiation monitor is inoperable for any reason, any person entering the teletherapy room shall use a properly operating portable survey instrument.

5) The survey instrument is to be tested each day it is used before use.

6) Full calibration measurements shall be performed yearly using a dosimetry system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.

7) Monthly spot-check measurements shall be performed using a dosimetry system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicist in Medicine within the previous two years or after any servicing or by a dosimetry system that has been calibrated by direct intercomparison within the previous one year with a system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicist in Medicine.

Full Calibration of the Teletherapy Unit

1) The teletherapy unit shall have full calibration measurement when:
   a) Prior to the first use of the unit for treating humans
   b) Prior to treating humans :
      (1) Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for physical decay;
      (2) Following replacement of the radiation source or following reinstatement of the teletherapy unit in a new location;
      (3) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components of the source exposure assembly; and
   b) At intervals not to exceeding one year.

2) Full calibration measurements shall include determination of:
   a) The dose rate to an accuracy within ±3 percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;
   b) The congruence between the radiation field and the field indicated by the light beam localizing device.
   c) The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
   d) Timer accuracy;
   e) The accuracy of all distance measuring devices used for treating humans; and
   f) The determination of transmission factors for wedges and trays.

3) Full calibration measurements shall be made in accordance with procedures and recommendations by Task Group 21 of the American Association of Physicists in Medicine (*Medical Physics*, December, 1983).

4) The dose rate values shall be corrected mathematically for physical decay for intervals not exceeding one month.

5) Full calibration measurements shall be performed yearly using a dosimetry system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.

Full Calibration of the Teletherapy Unit (cont.)

6) Full calibration measurements and the physical decay corrections shall be performed by Dennis Frieda, Ph.D. or an equivalent expert qualified by training and experience to calibrate a teletherapy unit. The licensee shall determine that the qualified expert:
   a) Is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics.; or
   b) Has the following minimum training and experience:
      1) A Master's or Doctor's degree in physics, biophysics, radiological physics, medical physics or health physics;
      2) One year of full time training in therapeutic radiological physics; and
      3) One year of full time experience in a radiotherapy facility including personal calibration and spot check of at least one teletherapy unit.

7) After full calibrations measurements that resulted from replacement of the source, or from a spot-check that indicated that the output differed by more than 5 percent from the output obtained at the last full calibration corrected for radioactive decay, an independent check of the output for a single specified set of exposure conditions should be performed. this independent check should be performed within 30 days following such full calibration measurements.
   The independent check will be performed by either:
   (1) A qualified individual who did not perform the full calibration using a dosimetry system other than the one that was used during the full calibration. The dosimetry shall have been calibrated within the previous two years and after any servicing that may have affected system calibration; or
   (2) A teletherapy physicist (or an oncology physician, dosimetrist, or radiation therapy technologist who has been properly instructed) using a thermoluminescence dosimetry service available by m[illegible] that is designed for confirming teletherapy doses and that is accurate within 5 percent.

Monthly Spot-Check of the Teletherapy Unit.

1) Spot-check measurements shall be performed on a monthly basis.

2) Spot-check measurements shall include determination of:
   a) Timer accuracy;
   b) The congruence of the radiation field and the field indicated by the light beam localizing device;
   c) The accuracy of all distance measuring devices used for treating humans;
   d) The dose rate for one typical set of operating conditions; and
   e) The difference between this measurement and the anticipated output, expressed as a percentage of the anticipated output.

3) Spot-check measurements shall be performed by Dennis Frieda, Ph.D. or an equivalently qualified expert.

4) The spot-check measurements shall be performed using a dosimetry system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicist in Medicine within the previous two years or after any servicing or by a dosimetry system that has been calibrated by direct intercomparison within the previous one year with a system that has been calibrated by a Regional Calibration Laboratory accredited by the American Association of Physicist in Medicine.

Leak Test Procedures.

1) The teletherapy source shall be tested for leakage at intervals not to exceed six months.

2) A Sealed Source Leak Test Kit obtained from Monitoring Services, Houston, Texas, will be used for taking the test sample. Their instruction for using the kit will be followed.

3) Source smears or wipes will be obtained by Dennis Frieda, Ph.D., Radiological Physicist, and taken from locations where contamination, if present, is likely to accumulate. This includes, but is not limited to, the inner surface of the beam collimating device, and the area near where the source is located when the source is in the "ON" position.

4) All test samples will be obtained with the source in the "OFF" position. Test samples will be taken with adequate precautions to minimize radiation exposure and spread of contamination.

5) Test samples will be returned to Monitoring Services, Houston, Texas, for counting and evaluation. Before mailing, all test samples will be monitored with a portable low-range survey meter or radiation monitor. If levels are in excess of twice background, the source will assume to be leaking and the licensee shall promptly take appropriate action to prevent the spread of contamination.

6) Records of each leak test will be maintained for at least two years.

Inspections and Servicing of the Teletherapy Unit

1) The teletherapy unit is to be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

2) This five year inspection and servicing of the teletherapy unit shall be performed by persons specifically licensed to do so by the Commission.

Limitations on Work Done on Teletherapy Unit.

Only persons or firms specifically authorized by the NRC are to perform the following services:

1) Install, relocate , or remove teletherapy units containing sources;

2) Perform source exchanges;

3) Perform any maintenance or repair on teletherapy unit that involves the source drawer, the shutter, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

Relocation of the Teletherapy Unit.

The NRC must approve any plans and the proposed location before the teletherapy unit is relocated or moved from its present location.

Radiation Survey Reports

1) Radiation survey reports shall be performed following each installation of a teletherapy source and prior to initiation of a treatment program.

2) A radiation survey shall contain, as a minimum, the information identified in Appendix F of Draft Regulatory Guide FC 414-4 dated December 1985.

3) Survey measurements shall be performed by Dennis Frieda, Ph.D. or an equivalent expert qualified by training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise on protection needs and who has good knowledge and understanding of the operating characteristics, including the limitations, of the radiation detection instrumentations and measuring devices that are used in the survey. The licensee shall determine that the qualified expert:
   a) Is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or
   b) Has the following minimum training and experience:
      (1) A Master's or Doctor's degree in physics, biophysics, radiological physics, medical physics or health physics;
      (2) One year of full time training in therapeutic radiological physics; and
      (3) One year of full time experience in a radiotherapy facility including personal calibration and spot check of at least one teletherapy unit.

4) A report of the survey results and tests shall be sent to the U.S. Nuclear Regulatory Commission, Region III, Materials Licensing Section, 801 Warrenville Road, Lisle, Illinois 60532-4351, not more than 30 days after each installation of a teletherapy source.

Recordkeeping.

1) The following records are to be maintained until the NRC authorizes their disposition:
   a) Personnel dosimetry records.

2) The following records are to be maintained until the NRC terminates the teletherapy license:
   a) Copies of NRC licenses, our license applications, and correspondence with the NRC in support of the license request.
   b) Records of daily checks of room beam-on monitor.
   c) Records of training of new personnel and annual refresher training of personnel.

3) The following records are to be maintained for five years after said action was performed:
   a) A record of each misadministration.
   b) Results of full calibration measurements.
   c) Records of the calibration of the dosimetry system used for full calibration measurements.
   d) Records of the licensee's evaluation of the qualified expert's training and experience.
   e) Copies of reports of surveys conducted in accordance with any installation of a teletherapy source.
   f) Records of the transfer of radioactive material.

4) The following records are to be maintained in an auditable form for three years:
   a) Records of each quality management review, including the evaluations and findings of the review.
   b) A record of the relevant facts and what corrective action, if any, was taken for each recordable event.
   c) Each written directive and the record of each administered radiation dose where a written directive was required.

5) The following records are to be maintained for two years after completion of said action:
   a) Records of results of daily safety device checks.
   b) Results of spot-check measurements.
   c) Records of the calibration or intercomparison of the dosimetry system used for spot-check measurements.
   d) Records of leak-test results.
   e) Records of survey instrument calibrations.
   f) Records of receipt of radioactive material are to be maintained for two years following transfer, or disposal of the radioactive material.

Emergency Procedures

1) All new teletherapy personnel are required to be trained in emergency procedures as soon as they report for duty.

2) Practice drills in emergency procedures are to be conducted with all appropriate personnel at least once a year.

3) The following emergency procedures are to be posted at the teletherapy unit console, and followed when necessary.

EMERGENCY PROCEDURES FOR BEAM CONTROL FAILURE OR MALFUNCTION

If the light signals or the beam-on monitor indicates that the beam control mechanism has failed to terminate the exposure at the end of the preset time (e.g., if the red light stays on and the green light is off, or if both the red and the green lights stay on for more than a few seconds) the source may still be in the "on" position. The following steps are to carried out promptly and in a calm manner by the Radiation Therapy Technologist:

1) Open the door to the treatment room.
2) If the patient is ambulatory, tell him or her to get off the table and leave the room.
3) If the patient is not ambulatory, enter the treatment room but avoid exposure to the direct beam. Pull the treatment table as far away from the direct beam as possible. Transfer the patient to a stretcher and remove the patient from the room.
4) Close the door and secure the area by locking the door to the treatment room or posting a guard at the entrance.
5) Turn off the main switch at the control panel.
6) Notify the radiation therapist, radiation safety officer and radiation physicist at once.
7) Conspicuously post a sign in the area to warn others of the problem.

Radiation Therapist and Radiation Safety Officer: Liep Tio, M.D.
Phone No.: On Duty: 257-7082 Off Duty: 257-7408

Radiation Physicist: Dennis Frieda, Ph.D.
Phone No.: On Duty: 1-882-9960 Off Duty: 1-882-7416

Procedures for Notifying the Proper Persons in the Event of an Accident or Unusual Occurrence

1) Report promptly to the radiation oncologist, the radiation safety officer, and the radiation physicist any unusual condition, malfunction or defect detected while using the teletherapy unit at any time.

2) The NRC Operations Center is to be notified as soon as possible but no later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposure to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

3) Theratronics (AECL) is to be contacted to perform any of the following services:
   a) Perform any maintenance or repair on teletherapy unit that involves the source drawer, the shutter, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels;
   b) Perform source exchanges; and
   c) Install, relocate, or remove teletherapy units containing sources.

4) The NRC Operations Center is to be notified by telephone within 24 hours after discovery of any of the following events involving licensed material:
   a) An unplanned contamination event that:
      (1) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
      (2) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of 20.1001-20.2401 of 10 CFR part 20 for the material;
      (3) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
   b) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
   c) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
      (1) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of 20.1011-20.2401 of 10 CFR part 20; and

Procedures for Notifying the Proper Persons in the Event of an Accident or Unusual Occurrence (cont.)

(2) The damage affects the integrity of the licensed material or its container.

d) Any misadministration.

5) The following reports must be made for any teletherapy misadministration.

a) Within 24 hours after discovering the misadministration, the licensee shall notified:

(1) The administrator of the hospital;
(2) The NRC Operations Center (phone #: (301) 951-0550);
(3) The referring physician of the affected patient; and
(4) The patient or a responsible relative (or guardian), unless the referring physician personally informs the licensee either that he will inform the patient or that, in his medical judgment, telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other. The licensee is not required to notify the patient without first consulting the referring physician.

b) Within 15 days after the initial therapy misadministration report to the NRC, a written report will be sent to:

(1) The NRC Regional Office;
(2) The patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee.

6) The following are the names and phone numbers of the appropriate people or organizations to contact:

a) Radiation Oncologist and Radiation Safety Officer: Liep Tio, M.D.
Phone No.: On Duty: 257-7082 Off Duty: 257-7408

b) Radiation Physicist: Dennis Frieda, Ph.D.
Phone No.: On Duty: 1-882-9960 Off Duty: 1-882-7416

c) Administration: Charles R. Brackney
Phone No.: On Duty: 257-6700

d) Theratronics (AECL) for service:
Phone No.: Dallas Regional Office: (214) 233-0939
Chicago Regional Office: (312) 593-3242

e) U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road, Lisle, IL
Phone No.: (708) 829-9500

f) U.S. Nuclear Regulatory Operation Center
Phone No.: (301) 816-5100

QMP

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OZARKS MEDICAL CENTER
RADIATION SAFETY OFFICER
P.O. BOX 1100
1100 KENTUCKY
WEST PLAINS, MO 65775

ATTN: KAILASH TARNEJA, M.D.

Docket Number: 3014280
License Number: 24-18733-01

Dear Dr. Tarneja:

This refers to the review of your written Quality Management Program (QMP) submitted in accordance with 10 CFR 35.32. A review of the QMP was performed to determine whether policies and procedures have been developed to meet the objectives of the rule. Based on this submission, there appear to be significant weaknesses and potential substantial failure of your QMP to meet the objectives in 10 CFR 35.32 in that:

Regarding I-125 and /or I-131 > 30 Microcuries

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a policy in your QMP.

Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the

radiopharmaceutical dosage. Your QMP must include a policy/ procedure that requires that revisions to written directives will be made prior to administration.

The dosage should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive; that is, the dosage should be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive. Please provide such (or similar) procedures in your QMP.

A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in an auditable form.

Your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10CFR 35.32(e).

To meet the requirements in 10 CFR 35.32, you may choose to utilize the procedures described in Regulatory Guide 8.33(enclosed), or submit procedures that are equivalent. If you choose to use Regulatory Guide 8.33, be certain that the procedures you select are adjusted to meet the specific needs of your program as necessary. Additionally, you are reminded that training and/or instruction of supervised individuals in your QMP is required by 10 CFR 35.25.

Due to the apparent failure of your written QMP to meet the objectives in 10 CFR 35.32, you must immediately modify your written QMP to address the items listed above, and provide those modifications to your NRC regional office within 30 days of the date of this letter. NRC will review these matters during your next routine NRC inspection to determine whether violations of NRC requirements have occurred. Enforcement action may be taken at that time for failure to meet the requirements of 10 CFR 35.32.

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Please be advised that this QMP will not be incorporated into your license by condition. This allows you the flexibility to make changes to your quality management program without obtaining prior NRC approval. When modifications are made to your program, You should submit any changes to your QMP to this Office within 30 days as required by 10 CFR 35.32(e).

Your QMP was reviewed by an NRC contractor following a standard review plan and related checklist provided by the NRC staff. This letter outlining the findings of that review was prepared by the contractor utilizing standard paragraphs previously reviewed and approved by NRC Headquarters and regional management.

If you have any questions, please call Region III at (708) 829-9887.

Sincerely,

John R. Madera, Chief
Materials Licensing Section

Enclosure: As stated

bcc w/o enclosure:

M. Lanza
S. Merchant, NMSS

RIII

Madera