

NEW YORK STATE DEPARTMENT OF HEALTH
BUREAU OF ENVIRONMENTAL RADIATION PROTECTION
RADIATION GUIDE 10.8, Rev. 1
GUIDE FOR THE PREPARATION OF APPLICATIONS FOR
MEDICAL TELETHERAPY PROGRAMS

INTRODUCTION

A. Purpose of Guide

This guide describes the type and extent of information needed by the New York State Department of Health staff to evaluate an application for a specific license to possess and use radioactive material in a teletherapy unit for the treatment of human beings. This type of license is provided for under Sections 16.120 and 16.121 of 10 NYCRR 16, "Ionizing Radiation."

The New York State Department of Health will issue a single radioactive materials license to cover an institution's teletherapy program. Separate licenses are not normally issued to different departments of a medical institution, nor are they issued to individuals associated with the institution. The license will be issued in the institution's name in all cases, except for private practices located outside an institution's premises. An institution's other medical programs will be covered in a separate license.

The applicant should carefully study the regulations and this guide, and should submit all information requested. The Department will request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation safety program. Such requests will delay final action on the application.

B. Applicable Regulations

All regulations pertaining to this type of license are found in Title 10, Chapter 1, Part 16 of the New York Code of Rules and Regulations (10 NYCRR 16). Chapter 1 is entitled "State Sanitary Code" and Part 16 is entitled "Ionizing Radiation." The statutory authority for the rules and regulations is found in the New York State Public Health Law, Section 225.

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C. As Low As is Reasonably Achievable (ALARA)

Item (a) of 10 NYCRR 16.5 requires that persons who operate or permit the operation of radiation installations shall make every effort to maintain radiation exposures and releases of radioactive material as far below the limits of Part 16 as is reasonably achievable.

1. General ALARA Considerations

Each individual who is authorized to use radioactive material should provide appropriate instruction to all individuals who work with or in the vicinity of radioactive material, and should ensure that the facility and equipment are adequate for safe use. Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or Radiation Safety Officer (RSO).

D. Licensee Responsibility for Radiation Safety and Quality Assurance in Medical Teletherapy.

The licensee shall ensure that only the person named as the Radiation Therapy Physicist for the license will perform full calibrations of the teletherapy unit(s) and provide decay-corrected output values. The physicist should also oversee quality control testing of equipment and participate in treatment planning. Each facility must have a written Quality Assurance Manual which fully describes the Quality Assurance Program. Management shall ensure that the Quality Assurance Program is implemented and shall audit the program annually.

The Department requires each licensee to conduct a radiation safety and quality assurance program adequate to protect health and safety. An essential component of such a program in radiation therapy facilities is that all persons who participate in the planning or administration of radiation therapy must be qualified by training and experience to perform these functions. There must also be clearly defined responsibilities for each person involved, a clear understanding of supervisory roles and adequate staffing for the therapy program. If your Radiation Therapy Physicist is a consultant or part-time employee, you should carefully consider whether the amount of time he or she devotes to your facility is adequate to support your program.

It is particularly important that all personnel who participate in treatment planning and dosimetry, especially when computers are used in the planning procedure, be closely supervised by the physicist named on the license or an authorized physician-user who has expertise with the system in use.

An authorized physician user, or a physician under the tutelage of an authorized user, must be available for consultation and supervision, either on the premises or nearby, when patients are receiving treatment.

The licensee is responsible for ensuring that all personnel are qualified and that supervision is adequate.

Appendix E - Part 1 contains the Quality Assurance Program for radiation therapy developed by the American College of Radiology. Wherever possible this program should be adopted.

Appendix E - Part 2 contains specific items which must be addressed in every Quality Assurance program.

RESPONSE. Describe your Radiation/Safety Quality Assurance Program and confirm that it will include procedures to address the items listed in Appendix E - Part 2. Wherever possible you should also commit to adopting the ACR Program described in Appendix E - Part 1.

E. Types of Radioactive Material Licenses

Licenses issued to physicians for private practice specify the radioisotopes and the clinical uses that may be performed by the physician to whom the license is issued. Such licenses are issued to physicians who meet the training and experience requirements in Appendix B and who are located in private offices and not on hospital premises. It is not required that a radiation protection committee be formed. The private practice license does not permit other physicians to obtain clinical radioisotope training and experience under it. Section 16.121 of 10 NYCRR 16 outlines specific requirements for this type of license.

Specific licenses of limited scope issued to institutions specify the radioisotopes and the clinical uses that may be performed by physicians named on the institution's license. The regulations of Section 16.120 of 10 NYCRR 16 require an institutional licensee to have a Radiation Protection Committee (see Appendix B to Radiation Guide 10.1) to evaluate all proposals for clinical research, diagnostic and therapeutic uses of radioisotopes within the institution.

The physicians named on the institution's license must meet the training and experience requirements in Appendix B and conduct their programs with the approval of the Radiation Protection Committee. Institutional licenses provide a means whereby other physicians, under the tutelage of physicians named on the license, may obtain basic and clinical radioisotope training and experience that may enable them to qualify as individual users.

FILING AN APPLICATION

A license application for specific licenses for human use should be submitted on Form GEN 307B "Application for Radioactive Materials License" and appropriate attachments. The applicant should complete all items on the application form in sufficient detail for the review staff to determine that the applicant's equipment, facilities, personnel training and qualifications, and radiation protection program are adequate to protect health and minimize danger to life and property.

For Items 5 through 25, submit the required information on supplementary pages. You should identify and key each separate sheet or document submitted with the application to the item number on the application to which it refers. All typed pages, sketches, and, if possible, drawings should be on 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8-1/2 x 11 inches.

One copy of the application, with all attachments, should be retained by the applicant, since the license will require as a condition that the licensee follow the statements and representations set forth in the application and any supplement to it. The original and one copy should be mailed to the Bureau of Environmental Radiation Protection, New York State Department of Health, Empire State Plaza, 421 Corning Tower, Albany, New York 12237.

CONTENTS OF AN APPLICATION

The following paragraphs explain the information requested on Form GEN 307B. The item numbers correspond to the appropriate section of the form. This guide contains several appendices that present sample procedures or sample programs. You may wish to adopt one or more of these samples as part of your program. If so, you may adapt the following paragraph as a response to the appropriate item in your application:

Item : We, (name of teletherapy applicant), have established and agree to follow the procedures for as described in Appendix of Radiation Guide 10.8 Rev. 1.

If you refer in your application to a section or appendix of this guide or of any regulatory guide, that section or appendix will be incorporated as a part of the terms and conditions of your license. You will be inspected against the commitments contained in the referenced section, appendix, or document, just as you will be inspected against your more detailed responses. Therefore, you must keep a copy of the referenced guide on hand at all times so that you can review your commitments as necessary and instruct staff in these requirements.

- 1a. ENTER the name, mailing address and telephone number of the applicant. If the request is for a private license, enter the name of the physician or partnership. It is particularly important that the mailing address be sufficiently complete so that all correspondence to the licensee will reach persons responsible for the radiation safety program.

- 1b. LIST the addresses and locations where radioactive material will be used or stored if other than the address stated in Item 1a. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use. The actual locations of use should be listed, whether or not they are the same as the mailing address in Item 1a: i.e., a post office box may be most suitable for Item 1a. in some cases, but this address does not adequately describe the location of use.
2. ENTER the name and telephone number (including area code) of the individual to be contacted about this application. This should be someone who is knowledgeable about your program and can answer questions.
3. INDICATE whether this is an application for a new license, an amendment, or a renewal.
4. a) STATE the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation safety program. The Radiation Safety Officer should be a member of the licensee's staff who is present when radioactive materials are in use.

b) STATE the name of the individual who will be the Radiation Therapy Physicist for the license. Only the person named may perform full calibrations of your teletherapy unit and provide decay-corrected output values. Enter the number of hours per week the the physicist will provide to your program. If you wish to have another physicist perform these functions you must first obtain an amendment to this license.
5. LIST the names of all persons who will use, supervise, or direct the use of radioactive material. This list should include the physicians who supervise other physicians in training and/or who direct technologists or other paramedical personnel who use radioactive material for human or nonhuman use. Professionals other than physicians may also be authorized to use radioactive material for nonhuman use.

Physicians authorized to use radioactive material have the following responsibilities:

- a. Examination of the patient and his or her medical records to determine if radiation therapy is appropriate;
- b. Prescription of the radiation dose and how it is to be administered (e.g. 5.000 rads to be delivered at the rate of 200 rads per day under specified conditions of field size, distance, angle, etc.);
- c. Regular review of the patient's progress and modification of the originally prescribed dose as warranted by the patient's reaction to the radiation;

5. d. Actual use of, or direction of technologists or other paramedical personnel in the use of, the teletherapy unit; and
- e. Provision of necessary follow-up medical care.

At institutions items a. through e. may be delegated to physicians who are in training under the tutelage of an authorized physician-user. The term "tutelage" means that the physician-user (1) has adequately instructed the physicians-in-training in the specific human use, (2) has ascertained that they are receiving training in the safe use of these materials in humans, and (3) periodically reviews the work of those supervised and assures himself or herself that proper medical records are made of each use. The licensee shall ensure that this is a formal program and that there is adequate documentation of items 1, 2 and 3.

The authorized physician-user may delegate to licensed radiotherapy technologists or physicists the following activities:

- a. Actual operation of the teletherapy unit for the treatment of humans.
- b. Overseeing administration of the radiation dose.
- c. Performance of physical measurements for dosimetry or treatment planning purposes; survey, spot-check, and other quality assurance checks and comparison or intercomparisons of dosimetry systems.

Items a. and b. may be delegated to a licensed radiotherapy technologist only.

6. Radioactive Material. You must provide certain details about each sealed source you are requesting and the teletherapy unit in which the source will be housed. You may find it convenient to provide the information requested in Items 6 and 7 by using the form shown in Appendix A of this guide.

Sealed Sources to be Used in Teletherapy Unit

SPECIFY for each sealed source to be used for teletherapy:

- a. The radionuclide (e.g., cobalt-60).
- b. The manufacturer's name and model number.
- c. The maximum amount of radioactive material in any one source; express this amount in curies.
- d. The maximum output for a source containing the maximum amount of radioactive material. Note that the output should be expressed in terms of roentgens per hour at 1 meter (RHM) or roentgens per minute at 1 meter (RMM).
- e. The total amount of radioactive material to be possessed at any one time; express this amount in curies. Applicants usually request a total possession limit that is twice the amount of the source in use. This permits possession of a second source stored temporarily at the facility during source exchange.

6. Teletherapy Unit

SPECIFY the manufacturer's name and the model name and number of the teletherapy unit in which each teletherapy source will be housed. SPECIFY whether the unit will have an integral beam absorber (beam catcher) or will have a counterweight. Each unit should have a minimum treatment distance of 80 cm or more and rotational capability. If any unit does not meet these criteria, limitations may be specified for its use or no use may be authorized. For each such unit describe proposed uses in detail (e.g. palliative treatment only) and any extenuating circumstances that would support licensing.

The teletherapy units should be keyed to the sources listed in Item 6.1.

NOTE: To speed the review of your application, you should verify with your supplier that your requested sealed source and teletherapy unit and your maximum activity per source and maximum source output combinations have been reviewed and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State. If your combination has not been approved, contact this office for additional guidance.

7. SPECIFY whether the teletherapy source will be used for treatment of patients only or whether it will also be used for other purposes. If you request other uses, describe them (e.g., irradiation of animals). The requested uses should be keyed to the sources listed in Item 6.1. You may find it convenient to provide this information using the form shown in Appendix A.
8. Radiation Safety Officer - The radiation safety officer may be either a staff radiation therapy physicist or an authorized physician user named on the license. See Appendix B, Section 2 for minimum qualifications. Even if the licensee employs a consultant to assist the Radiation Safety Officer, the licensee remains responsible for the Radiation Safety Program as required by the license.
9. Training and Experience.
- a. Authorized users(s). If the physician has been previously authorized to use the radioactive material requested in this application, it is necessary to SUBMIT only the previous license number if issued by the New York State Health Department, or a copy of the complete license if issued by another licensing agency.

If the physician has not been previously authorized to use the radioactive material requested, STATE where he/she is licensed to practice medicine, and SUBMIT a complete description of his/her training and experience. Use Supplements B and C to describe the physician's training and experience. Criteria for acceptable training and experience are contained in Appendix B, Section 3 to this guide.

9. Training and Experience Continued.

- b. Radiation Therapy Physicist. SUBMIT the training and experience of the person or persons who will be the radiation therapy physicist for this license. See Appendix B Section 4.

This should include copies of any diplomas and board certifications earned.

- c. Radiation Therapy Technologists. Only a person who holds a license to practice radiotherapy technology, issued by the New York State, Department of Health, may operate teletherapy devices in the treatment of humans.

- d. Personnel Training Program. You must establish and agree to follow written procedures for instructing individuals as required by Section 16.13 (10 NYCRR 16). As a minimum, these written procedures should, require:

- 1) That individuals who work in or frequent restricted areas (e.g. physicians, technologists) be instructed in the items specified Section 16.13 (10 NYCRR 16) at the time of initial employment and at least annually thereafter.
- 2) That this instruction include all written procedures developed as a prerequisite for obtaining your New York State Radioactive Materials License and other terms of the license pertinent to radiation safety.
- 3) That other individuals whose duties may require them to work in the immediate vicinity of licensed material (e.g. housekeeping, security, clerical personnel) be informed about radiation safety hazards and appropriate precautions at the time of their initial employment and at least annually thereafter.
- 4) That, until New York State terminates your teletherapy license, you maintain records documenting initial and refresher training and that, as a minimum, these records identify the individual who conducted the training, the individuals who were trained, the date and duration of the training, and the topics covered.

RESPONSE. Submit one of the following:

- 1) A statement that you have adopted the training program described in Appendix C of Radiation Guide 10.8, Rev. 1.
- 2) A copy of appendix C to Radiation Guide 10.8, Rev. 1 with your changes indicated in red ink.
- 3) A copy of the personnel training program that you have established and that you agree to follow for instructing individuals as required by Section 16.13 (10 NYCRR 16).

10. Instrumentation and Calibration

a. Instrumentation. You must agree to have the following radiation detection instruments in your possession and available for use:

- 1) A portable low-range survey meter capable of detecting 0.2 milliroentgen per hour.
- 2) A beam-on radiation monitor permanently mounted in each teletherapy room that is equipped with an emergency power supply separate from the power supply for the teletherapy unit. The beam-on monitor must be capable of providing a visible indication (e.g., flashing light) of an exposed or partially exposed source, and the visible indicator must be observable by a person entering the teletherapy room.
- 3) A dosimetry system for making full calibration and spot-check measurements (or have access to it).
- 4) An instrument of sufficient sensitivity to count leak-test samples, e.g., a NaI (Tl) well crystal connected to a single or multichannel analyzer (or have access to it).
- 5) A high-range portable survey meter such as an ionization-type instrument capable of reading at least 1 roentgen per hour (or have access to it).

RESPONSE. Your response to Item 10. a. should be:

- 1) A description of the radiation detection and measuring instruments that you will use for radiation protection and dosimetry, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control. You do not need to identify these instruments by manufacturer's name and model number.

If you will not have all instruments in your possession, describe how you will have access to each of them.

b. 1) Calibration of Survey Instruments.

Appendix H to this Guide contains procedures for calibrating survey instruments. STATE that you will follow the model procedures or submit a copy of the model procedure with your changes indicated in red ink.

10. b. 2) Calibration of Dosimetry Equipment

(a) A licensee must have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

i. The system must have been calibrated by the National Bureau of Standards or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

ii. The system must have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Bureau of Standards or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2%. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(b) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph b. 2) (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph b. 2) (a) of this section.

10. b. 2) (c) The licensee shall retain a record of each calibration, intercomparison, and comparison for a period of 3 years. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs b. 2) (a) and b. 2) (b) of this section, the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

RESPONSE. Confirm that you will have a dosimetry system(s) available for calibrations and spot-checks of your teletherapy unit which has been calibrated in accordance with Item 10. b. 2 of Radiation Guide 10.8, Rev. 1.

11. Facilities and Equipment. 10 NYCRR 16.103 (a) states that an application will be approved, if, among other things, the applicant's proposed facilities and equipment are adequate to protect health and minimize danger to life or property. In order to evaluate the adequacy of your proposed facilities and equipment, you must provide a detailed description as discussed below.

a. Description of Facility. Annotated plans and elevation drawings or sketches should provide sufficient information for staff to evaluate the proposed facility. As a minimum, the plans and elevation drawings or sketches of the teletherapy facility* should show:

- 1) The scale to which the drawings are made. Use the same scale for all drawings; the recommended scale is 1/4 inch = 1 foot.
- 2) The direction of north.
- 3) The location of the teletherapy unit and source within the treatment room.
- 4) The directions of primary beam usage and, in the case of an isocentric unit, the plane of beam rotation.
- 5) The type, thickness, and density of the shielding materials used on all sides of the treatment room, including the floor and ceiling.
- 6) The location of doors, windows, conduits, and other penetrations and voids in the shielding materials.

*As used in this guide, the term "teletherapy facility" means the treatment room and its surroundings. The term "treatment room" refers to the room in which the teletherapy unit and source are located and patients are treated.

11. 7) The nature of and distances to all areas adjacent to the treatment room (including above and below). Note that plans and elevation drawings are particularly helpful in showing the relationship among the treatment room, the roof, and the rest of the building.
- 8) The height of earth against outside walls, if applicable.
- 9) The type of use of all areas adjoining the treatment room, including areas above and below. Identify all areas as controlled or noncontrolled.

RESPONSE. If this is an original application, or if changes have been made in the facility, you should submit annotated plans and elevation drawings or sketches of the proposed teletherapy facility that include the information listed above. Do not submit blueprints.

- b. Viewing System. You must provide a viewing system that permits continuous observation of the patient from the operator's position while the patient is being treated.

RESPONSE. Describe the system you will use to view the patient continuously. If you will use a shielded viewing window, and this is an original application, also specify the thickness, density, and type of material used. If you will use a closed circuit television system (or other electronic system) for viewing the patient, also describe the back-up system you will use in case the electronic system malfunctions or specify that treatments will be suspended until the electronic system is repaired and functioning again.

- c. Warning Systems and Access Controls. You must provide adequate equipment and controls to maintain exposures of radiation to workers within regulatory limits.

Each door leading into the treatment room must be provided with an interlock to control the "on-off" mechanism of the teletherapy unit. The interlock must cause the source to move to the "off" condition if the door to the treatment room is opened when the source is exposed. The mechanism must be wired so that the source cannot be returned to the "on" condition until the door is closed and the system is reset at the control panel.

RESPONSE. Describe (1) warning systems (e.g., locks, signs, warning lights, and alarms, interlock systems) for each teletherapy treatment room; and (2) methods for controlling occupancy for each controlled area. If other radiation-producing equipment (e.g., linear accelerator, x-ray machine) is located in the treatment room, describe the steps that will be taken to ensure that no two units can be operated simultaneously.

*As used in this guide, the term "teletherapy facility" means the treatment room and its surroundings. The term "treatment room" refers to the room in which the teletherapy unit and source are located and patients are treated.

11. d. Cont'd

Beam Stops. It may be necessary to restrict use of the teletherapy unit's primary beam because the treatment room's walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. Electrical, mechanical, or other physical means (rather than administrative controls) must be used to limit movement or rotation of the unit to ensure compliance with 10 NYCRR 16.6 and 16.7.

RESPONSE. If this is an original application, or if changes have been made in the facility, describe the mechanical or electrical beam stops that are operational and restrict beam orientation, specify the direction in which the teletherapy head can be moved, and describe the maximum angle (from vertical) of the beam orientation in each direction. Identify the angle orientation convention (e.g., 0 is vertical toward the floor, 90 is horizontal toward the east wall, 180 is vertical toward the ceiling, and 270 is horizontal toward the west wall). If the teletherapy unit has an integral beam absorber (also called a beam catcher), provide similar information for those orientations in which (1) the primary beam is directed toward the integral beam absorber, and (2) the primary beam is directed away from the integral beam absorber. You may use sketches to describe how beam stops limit the use of the primary beam.

Sample Responses. Some applicants have found it helpful to have a "sample" response on the use of a rotational unit with an integral beam absorber; the angle orientation convention described above applies.

For the primary beam directed toward the integral beam absorber, electrical or mechanical stops are set so that the primary beam must be centered (within plus or minus 2) on the integral beam absorber and, in that configuration, the attenuated primary beam may be rotated 360 pointing toward the floor, east wall, ceiling and west wall.

For the primary beam directed away from the integral beam absorber, electrical or mechanical stops permit the unattenuated primary beam to be directed in a 95 arc from 5 toward the west wall to vertically down toward the floor to 90 toward the east wall.

Experience has shown that, given this type of example, many applicants can make changes to accommodate their own situations (e.g., use of a vertical unit, use of a rotational unit without an integral beam absorber).

- e. Adequacy of shielding. Based on an evaluation of shielding and the planned use of each area, you must have determined whether each area adjacent to the treatment room will be maintained as a controlled or noncontrolled area, and you must demonstrate compliance with Part 16. Accordingly, if this is an original application or if changes have been made in the facility:

11. e.
 - 1) Each area adjacent to the treatment room (including above and below) must be identified as a controlled or noncontrolled area.
 - 2) The maximum radiation levels expected in each adjacent area must be calculated. The calculations should include:
 - (a) Maximum anticipated workload data.
 - (b) Your assigned values for each parameter used in the calculations such as beam orientation, maximum field size, scatter angle, scatter ratio, distance to scatterer, distance to area of concern, type and thickness of materials used in barrier, and transmission factor of barrier.
 - (c) Contributions from primary, leakage, and scattered radiation.
 - (d) Separate calculations for each area adjacent to the treatment room, including above and below the room. (Calculations need not be made for areas that have not been excavated.)
 - (e) "Worst case" situations.
 - (f) A consideration of continuous occupancy (e.g. occupancy factor of unity) for noncontrolled areas.
 - (g) Results expressed in millirems in any 1 hour and millirems in any 1 week.
 - 3) For each noncontrolled area, there must be a demonstration that the requirements of 10 NYCRR 16.7 will be met.
 - 4) For each controlled area, you must have a program covering access controls, signs, personnel training and monitoring, and surveys.

RESPONSE.

- 1) Identify each area adjacent to the treatment room (including above and below) as a controlled or noncontrolled area.
- 2) Submit calculations of the maximum radiation levels expected in each adjacent area. Your calculations should include:
 - (a) Maximum anticipated workload data (e.g., maximum number of patients treated per hour and per week; maximum dose and treatment time per patient; maximum "on time" per hour and per week).

11. e. RESPONSE (Continued)

- 2) (b) The value of each parameter used in your calculations. These parameters include such factors as beam orientation, maximum field size, scatter angle, scatter ratio, distance to scatterer, distance to area of concern, type and thickness of materials used in barrier, and transmission factor of barrier.
 - (c) Contributions from primary, leakage (with the source in the "on" position), and scattered radiation (including low-angle scatter that just misses the integral beam absorber).
 - (d) Calculations for each area adjacent to the treatment room, including above and below the room, and a statement as to whether the area will be maintained as a controlled or noncontrolled area. Calculations need not be provided for areas that have not been excavated.
 - (e) "Worst case" situations (e.g., use of maximum beam size; all patients treated in 1 hour using the critical orientation that produces high radiation levels in an adjacent area; if the integral beam absorber is not used for all patient treatments, calculations based on use of the unattenuated primary beam where appropriate; situations within the capabilities of the teletherapy unit that are not prohibited by electrical or mechanical stops.)
 - (f) A consideration of continuous occupancy (e.g., occupancy factor of unit >1) for noncontrolled areas.
 - (g) The results of each calculation expressed in millirems in any 1 hour and millirems in any 1 week.
- 3) For each noncontrolled area, state how you will meet the requirements of 10 NYCRR 16.7.
 - 4) For each controlled area, describe your program for meeting the requirements of 10 NYCRR 16.6. This description should include:
 - (a) The physical and administrative controls used to restrict access to the controlled area.

11. e. RESPONSE (Continued)

- 4) (b) The number, wording, size, and location of warning signs to be placed in the vicinity of the controlled area.
- (c) Your program for ensuring that personnel entering the controlled area receive proper instruction in accordance with 10 NYCRR 16.13.
- (d) Your program for ensuring that personnel entering the controlled area are monitored in accordance with 10 NYCRR 16.11.
- (e) The surveys that will be performed in accordance with 10 NYCRR 16.10

NOTE:

Radiation levels in noncontrolled areas must be such that a person in the area will receive a radiation dose exceeding neither 2 millirems in any 1 hour nor 100 millirems in any 7 consecutive days if the person were continuously present in the area.

In showing compliance you:

- 1) Must use an occupancy factor of unity because 10 NYCRR 16.7 (a) (2) assumes that a person is continuously present, and
- 2) May take advantage of "on time" (e.g. that fraction of an hour or week during which the primary beam of radiation is "on").
- 3) May use a fractional use factor (i.e. the fraction of the time during which the primary beam is directed at a particular barrier) to show compliance with the "100 millirems in any 7 consecutive days" requirement.

12. NA

13. NA

14. General Rules for the Safe Use of Radioactive Materials. Operating Procedures. Emergency Procedures and Quality Assurance Program.

a. Operating Procedures. You must establish and agree to follow written procedures governing the operation of the teletherapy unit. You should have written operating procedures directed to, and given to, specific groups of staff members (e.g., radiotherapy technologists) outlining the responsibilities of each group to ensure your compliance with New York State's regulations, the terms and conditions of the license, and the commitments made in license applications and correspondence with the Department. Many topics pertaining to radiation safety should be addressed in the operating procedures. As a minimum, these written procedures should:

- 1) Require that the teletherapy unit, room, and console be secured when unattended.
- 2) Describe the actions to be taken to ensure that only the patient is in the treatment room when the primary beam is turned on.
- 3) Require that safety devices be checked for proper operation (including identifying the devices to be checked and by whom, how the checks are to be performed and the frequency), that malfunctions or defects be corrected promptly, and that the dates and results of the checks and a notation of the date on which each malfunction or defect was corrected be maintained for at least 3 years after each check, and each correction of a malfunction or defect.

Appendix D contains a list of topics that must be addressed in a set of operating procedures. SUBMIT a copy of your operating procedures.

b. Emergency Procedures. 10 NYCRR 16.122 (e) requires that emergency procedures be established and that the procedures be posted at the control console. You must establish and agree to follow written procedures for emergencies that may occur, e.g., the teletherapy source fails to return to the "off" position. These procedures, designed to minimize radiation exposure to patients, workers, and the general public, should as a minimum:

- 1) Specify when they are to be followed.
- 2) Describe step-by-step actions that are to be taken and by whom.

14. b. 3) Give first consideration to minimizing the exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position). If a first step of the emergency procedures specifies pressing the "emergency bar" on the teletherapy unit console, this action may cause the source to return to the off position but may also cut power to the entire teletherapy unit or to the gantry or the couch--these possibilities must be considered in developing emergency procedures.
- 4) Instruct the staff to act quickly and calmly and to avoid the primary beam of radiation.
- 5) Require that, as soon as the patient and staff are out of the treatment room, the area be secured (e.g., door locked, guard posted) and a sign posted to alert others to the problem).
- 6) Specify who is to be notified. Provide the names of at least two individuals who can be notified and their on-duty and off-duty telephone numbers.

SUBMIT a copy of your emergency procedures; or state that you will follow the emergency procedures described in Appendix F of Radiation Guide 10.8, Rev. 1. The emergency procedures shown in Appendix F fulfill the criteria established above.

15. NA

16. Surveys and Inspections. 10 NYCRR 16.122 requires you to perform a radiation survey and to submit a survey report prior to initiation of a treatment program and subsequent to each installation of a teletherapy source. Section 16.10 (a) (2) requires a survey whenever any change is made in the installation or its use that might increase radiation levels.

The information contained in such survey reports should correspond to the information identified in Appendix G.

RESPONSE. Describe the information you will include in survey reports or state that you will include all the information described in Appendix G, of Radiation Guide 10.8, Rev. 1.

10 NYCRR 16.122 (d) requires that each teletherapy machine be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to ensure proper functioning. This inspection and servicing, as well as any service that could compromise the safety of the unit, must be performed only by persons specifically licensed by NRC or an Agreement State to do so. Each licensee must ensure that these requirements are complied with, and any repairs found to be necessary are promptly made.

Each teletherapy machine must be maintained in accordance with a schedule recommended by the manufacturer. Critical components such as the field light cord reel, source drawer solenoids, air pressure switch, air hoses and fittings, and treatment timer should be replaced periodically according to the recommended frequency.

RESPONSE. State that you will maintain your teletherapy machine(s) according to the recommended service schedule, and that a full inspection and service will be performed as required.

17. Waste Disposal. Most teletherapy licensees dispose of unneeded sealed sources by transferring them to the source manufacturer. You should note that 10 NYCRR 16.122 requires that certain work, including source removal or source exchange, may be performed only by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to do the work. Note also, that some teletherapy units contain radioactive material in the form of depleted uranium used as shielding material in the unit.

RESPONSE. Describe how you will dispose of unneeded teletherapy units and sources.

18. NA

19. NA

20. NA

21. NA

22. Other Procedures and Precautions

- a. Non-human Use. Some licensees in research facilities may plan to use the teletherapy unit for irradiation of animals, cells, etc. If you wish to perform such procedures you should have specified these uses in Item 7 of this application, and named the users in Item 5.

SUBMIT a description of the non-human uses you propose and the radiation safety procedures that will be followed.

- b. Leak-testing of Sealed Sources. Appendix I to this Guide contains a model procedure for performing leak tests. STATE that you will follow the model or submit a copy of the appendix with your changes indicated in red ink.

23. Personnel Monitoring Program. You must establish and agree to follow written procedures for personnel monitoring. As a minimum, these written procedures must require:
- a. That whole-body badges (e.g., film or thermoluminescent dosimeters, also called "TLDs") be provided to personnel who enter restricted areas under the circumstances described in 10 NYCRR 16.11.
 - b. That whole-body badges be exchanged for processing at intervals not to exceed 1 month.
 - c. That whole-body badges be processed by a commercial personnel dosimetry service company accredited by the National Voluntary Laboratory Accreditation Program (NVLAP).
 - d. That any pocket dosimeters used to measure exposure from licensed material be operable, calibrated, and tested for drift at intervals not to exceed 1 year. Records of calibration and drift tests must be maintained as described in 10 NYCRR 16.14.
 - e. That whole-body badges will be returned for processing immediately following any incident (such as a stuck source) which results in a non-routine radiation exposure to the wearer.

RESPONSE. Describe your personnel monitoring program.

24. NA

25. ALARA (As Low As is Reasonably Achievable) in medical institutions. Each institutional medical licensee must have a formal ALARA program. To our knowledge all medical institutions with cobalt teletherapy licenses will have other licenses with the Department. Therefore, information on your institutional ALARA program and Radiation Safety Committee will have been submitted already. If this is not the case, contact this office for further information.
26. CERTIFICATE. If the application is for a private practice, it should be signed by a senior partner or the president. If the application is for an institution, hospital, or medical center, it must be signed by its director or chief executive officer. Identify the title of the office held by the individual who signs the application.

AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make any changes in the facilities, equipment (including types of monitoring and survey instruments), procedures, authorized users or radiation safety officer, or radioactive material to be used.

Applications for license amendments may be filed either on the application form, or in letter form. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page and paragraph.

Amendment applications must be signed as described in Item 26 and dated. An original and two copies of the application for amendment should be prepared, and the original and one copy should be submitted, as in the cases for new or renewal applications.

RENEWAL OF A LICENSE

An application for renewal of a license should be filed at least 30 days prior to the expiration date. This will ensure that the license does not expire until final action on the application has been taken by the New York State Health Department as provided for in 10 NYCRR 16.105.

Renewal applications should be filed on Form GEN 307B appropriately supplemented, should contain complete and up-to-date information about the applicant's current program, should meet all licensing and regulatory requirements in effect at the time of renewal, and must be signed as described in Item 26 and dated. Renewal applications should also include the physician-user's training and experience or make a clear and specific reference to previous applications on which individual users received approval.

In order to facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information (except for previously approved users). If such references cannot be avoided, they are acceptable provided:

- a. The reference is made in response to a particular item of required information (e.g. bioassay procedures);
- b. The reference is clear and specific (e.g., title of document, date of submission, page and paragraph); and
- c. The referenced document contains all information required for a particular item at the time of renewal.

Prepare an original and two copies of the application. Retain one copy of the application, with all attachments, because the license will require, as a condition, that the institution follow the statements and representations set forth in the application and any supplements to it. Mail the original and one copy to the Bureau of Environmental Radiation Protection, New York State Health Department, Empire State Plaza, 421 Corning Tower, Albany, New York 12237.

LICENSE TERMINATION REQUESTS

Submit a signed Form GEN 322 indicating the disposition of the radioactive material. Form GEN 322 is available from the Bureau of Environmental Radiation Protection, New York State Health Department.

Submit survey results showing that all previously occupied areas are free of contamination and all sources of radioactive material have been removed in accordance with 10 NYCRR 16.10. A decontamination guide is available from the Bureau of Environmental Radiation Protection, New York State Health Department.

Such submissions must be made at least 30 days prior to relinquishing possession or control of premises where radioactive material is or has been stored or used.

APPENDICES

- APPENDIX A Description of Sealed Sources, Teletherapy Units, and Proposed Uses
- APPENDIX B Acceptable Training and Experience for Medical Teletherapy Personnel
- APPENDIX C Personnel Training Program
- APPENDIX D Topics that may be Included in Operating Procedures
- APPENDIX E Part 1 - American College of Radiology Quality Assurance Program
Part 2 - Basic Quality Assurance Program
- APPENDIX F Emergency Procedures for Beam Control Failure or Malfunction
- APPENDIX G Teletherapy Survey Reports
- APPENDIX H Model Procedure for Calibrating Survey Instruments
- APPENDIX I Leak-Testing Procedures

APPENDIX A

DESCRIPTION OF SEALED SOURCES, TELETHERAPY UNITS,
AND PROPOSED USES

Item 6 SEALED SOURCES TO BE USED IN TELETHERAPY UNITS

Radionuclide (element & mass no.)	Name of Source Manufacturer	Source Model Number	Maximum Activity per Source (in curies)	Maximum Output of Source (in RHM)	Number of Sources
(A)					
(B)					
(C)					

Item 6 TELETHERAPY UNITS

Name of Manufacturer (include description, if unit is custom made)	Model Name and Number	Minimum SSD or SAD	Beam Catcher (check one)	Counter- Weight of these)
(A)				
(B)				
(C)				

Item 7 PROPOSED USES

A	B	C	Check As appropriate
			Treatment of Patients Only
			Treatment of Patients and Other Use (as described below)

APPENDIX B

ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL TELE THERAPY PERSONNEL

1. General Criteria

Any human use of radioactive material (e.g., the internal or external administration of radioactive material, or the radiation therefrom, to human beings) must be carried out by or under the supervision of a professional practitioner. Such application of, or order to apply, radiation shall be in the course of the practitioner's professional practice and shall comply with the provisions of the license or other authorization of the practitioner under the Education Law of New York State.

10 NYCRR 16.120 (d) provides that the Department will approve a license application by an institution for medical use of radioactive material if it determines among other things that the professional practitioner designated as the individual user is adequately trained and experienced. Outlined below are training and experience criteria that the Department, with the assistance of its Radiological Health Advisory Committee, has found acceptable for physicians who use or direct the use of radioactive materials in teletherapy units.

This training and experience must have been obtained within a 5-year period preceding the date of the license application or must be supplemented by continuing education or experience. The original training and experience may have been satisfied concurrently by participating in a formally integrated 6-month training program (3-month if begun prior to July 1, 1984), in an accredited medical institution.

Any individual wishing to qualify as Radiation Safety Officer (RSO) must meet certain minimum training and experience criteria as outlined in section 2 of this appendix. This training and experience must have been obtained within a 5-year period preceding the date of the application or he/she must have had continuing involvement in radiation safety since the time of the training. An authorized user is automatically determined to have met the minimum training and experience criteria for RSO qualification.

Any individual wishing to qualify as Radiation Therapy Physicist must meet the training and experience criteria outlined in Section 4 of this appendix. This training and experience must have been obtained within a 5 year period preceding the date of the application or he/she must have had continuing involvement in radiation therapy physics since the time of the training.

2. Radiation Safety Officer

- a. A radiation therapy physicist who is a member of licensee staff and meets the criteria outlined in Section 4 below, or
- b. An authorized physician user who meets the criteria outlined in Section 3. below, shall be considered to have met the training and experience requirements for Radiation Safety Officer.

3. Proposed Users - Human Use

- a. Physicians specifically listed within the preceding 5 years as authorized users on a teletherapy license issued by the Nuclear Regulatory Commission, or an Agreement State are considered to have adequate training and experience. Specify the number of the New York State license, or submit a copy of any other license.
- b. Medical Specialty Board Certification

The following certifications will be accepted as evidence that a physician has had adequate training and experience:

- 1) Certification by the American Board of Radiology (ABR) in radiology or therapeutic radiology.
- 2) Certification by the American Osteopathic Board of Radiology (AOBR) in radiation oncology.
- 3) Certification by the Canadian Royal College of Physicians and Surgeons (RCPS) in therapeutic radiology.
- 4) Certification as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR).

Physicians holding one of the medical specialty certifications listed above should submit a copy of their certificates and, in the case of physicians who are FFR or FRCR, evidence of specialization in radiation therapy.

3. c. Physicians Who Do Not Meet the Criteria in Sections a. or b. - Minimum Training and Experience

The training and experience described below should have been received within 5 years of the date of application or the applicant physician must provide evidence of (1) continuing clinical involvement in radiotherapy (e.g., completed signed Supplement C forms) (a copy of Supplement C is included in this appendix and it may be reproduced as needed) or (2) having taken refresher or continuing education courses in radiation therapy.

- 1) Training in basic radioisotope handling techniques applicable to the use of sealed sources (200 hours) consisting of lectures, laboratory sessions, discussion groups, or supervised on-the-job training (OJT) experience (note that OJT must have been received in a formal training program) in the following areas:

i. Radiation physics and instrumentation	110 hours
ii. Radiation protection	40 hours
iii. Mathematics pertaining to the use and measurement of radioactivity	25 hours
iv. Radiation biology	25 hours

(The hours listed next to each of the four subjects above are suggested values and should not be interpreted as specific requirements.)

- 2) Experience with the types and quantities of radioactive material for which the application is made or equivalent (500\hours). This experience should include the following:
 - i. Review of full calibration and periodic spot-check measurements of teletherapy units,
 - ii. Review of source calibration of sealed sources other than teletherapy sources that are used for treatment purposes,
 - iii. Checking and using ion chambers and survey meters,

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3. c. 2) iv. Preparation of treatment plans and calculation of treatment times for teletherapy and brachytherapy*. and
- v. Learning appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources.
- 3) Clinical training in teletherapy procedures: Active practice in therapeutic radiology and 3 years of supervised clinical experience, which includes: 1 year in a formal training program accredited by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:
 - i. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
 - ii. Selecting the proper dose and how it is to be administered;
 - iii. Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and
 - iv. Post-administration follow up and review of case histories.
- d. Physicians Who Do Not Meet Criteria in Sections a. or b. - Documenting Training and Experience

The qualifications of each applicant physician who has not been previously approved by a licensing agency (see Section a.) and who is not certified (see Section b.) will be reviewed on a case-by-case basis with the assistance of the Radiological Health Advisory Committee to the Bureau of Environmental Radiation Protection. Supplements B and C may be used to provide much of the needed information. The following is a checklist of materials that should be submitted, with suggestions for preparation:

*Although brachytherapy procedures are not authorized on a teletherapy license, information on the applicant physician's experience with these procedures is important because the normal method of treatment of some patients (e.g., patients with cervical cancer) involves use of both brachytherapy and teletherapy).

1) Completed Supplement B Form

In Item 4, document at least 200 hours of training in basic radioisotope handling techniques, as described in Section c. 1. For each subject covered in this training, state where the training was obtained, the dates, total number of hours, and type of training. Hours should be broken down into lecture, laboratory, or OJT. OJT must have been obtained in a formal training program. Be sure that hours of training can be traced to the institution where the training was received. Each hour of training should be listed under only one subject category (e.g., the most applicable category).

In Item 5, document at least 500 hours of experience with the types and quantities of radioactive materials being requested as described in Section c. 2.

2) Completed signed Supplement C Forms

Supplement C forms are used to document clinical experience described in Section c. 3. Separate Supplement C forms should be completed and signed by each preceptor physician under whom the applicant physician gained training and experience.

3) Letters of Evaluation from each Preceptor Physician

These letters should describe the scope and extent of the applicant physician's training and experience as known by the preceptor physician and include the preceptor physician's evaluation of the applicant physician's competence to independently use teletherapy and brachytherapy sources for patient treatment.

4) For applicant physicians who completed their training and experience more than 5 years before the date of the application, evidence of (a) continuing clinical involvement in radiation therapy from the time the training was completed to the date of the application (e.g., completed signed Supplement C forms) or (b) having taken refresher or continuing education courses in radiation therapy (e.g., completed Supplement B form).

4. Radiation Therapy Physicist

- a. A person who is certified by a recognized certifying organization, in a branch of medical physics which deals with (1) the therapeutic application of roentgen rays, gamma rays, electron or other charged particle beams, neutrons, and radiation from sealed radionuclide sources; and (2) the equipment associated with the production and use of these radiations; or
- b. A person having equivalent qualifications as determined by the New York State Department of Health.



**SUPPLEMENT B
TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER**

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE <i>IF APPLICABLE</i>
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3. CERTIFICATION		
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES <i>(To be completed by individual providing training)</i>			
FIELD OF TRAINING	LOCATION AND DATES OF TRAINING	TYPE AND LENGTH OF TRAINING	
		LECTURE/LABORATORY COURSE <i>(Hours)</i>	FORMAL SUPERVISED Q/LABORATORY EXPERIENCE <i>(Hours)</i>
RADIATION PHYSICS AND INSTRUMENTATION			
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			

5. EXPERIENCE WITH RADIOACTIVE MATERIALS* <i>(Actual use of radioisotopes or equivalent experience)</i>				
ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

- * Experience with sealed radioactive sources under the supervision of qualified individuals should include:
- | | |
|--|--|
| <ol style="list-style-type: none"> 1. Review of sealed source construction and methods for check measurements of radioactivity levels. 2. In-use source checkings of sealed sources other than radiotherapy sources that are used for treatment purposes. 3. Calibration of ion chambers and survey meters. | <ol style="list-style-type: none"> 4. Preparation of treatment plans and treatment units for brachytherapy. 5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources. |
|--|--|

6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF *(Signature of proposer/submitter)*

TYPED OR PRINTED NAME	DATE		
NAME OF INSTITUTION			
MAILING ADDRESS			
CITY	STATE	ZIP CODE	RADIOACTIVE MATERIALS LICENSE NUMBER

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States or to any matter within its jurisdiction.

**SUPPLEMENT C
PRECEPTOR STATEMENT**

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS FULL NAME <hr/> STREET ADDRESS <hr/> CITY STATE ZIP CODE	KEY TO COLUMN C PERSONAL PARTICIPATION SHOULD CONSIST OF: 1. Supervised performance of services to determine the suitability for radioactive therapy and responsibilities on cases to be precepted. 2. Consideration in selection of radionuclide, radionuclide measurement, and modification of the therapy prescribed case to be precepted to suit the patient. 3. Followup of patients when required. 4. Study and discussion with preceptor of case histories to establish the most appropriate therapy procedure, technique, contraindications, etc.
--	--

2. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN CITED ABOVE IN USING SOURCES OR DEVICES FOR THERAPY			
ISOTOPE A	TYPES OF TREATMENT B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Add additional information, if necessary) D
Co-60 OR Co-137	COURSES OF TELETHERAPY TREATMENT		
	INTERSTITIAL		
	INTRACAVITARY		
I-125 Ir-192 OR Au-198 SEEDS	INTERSTITIAL		
Po-210	INTRACAVITARY		
X-RAY AND ACCELERATOR THERAPY	COURSES OF THERAPY TREATMENT		
S-80	SUPERFICIAL EYE CONDITIONS		
OTHER			

DATES AND TOTAL NUMBER OF HOURS IN CLINICAL TRAINING USING SEALED SOURCES FOR THERAPY

3. PRECEPTOR'S CERTIFICATION			
NAME OF SUPERVISOR	NAME OF INSTITUTION	RADIOACTIVE MATERIALS LICENSE NUMBER	
MAILING ADDRESS	CITY	STATE	ZIP CODE

I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF AND THAT I WAS AUTHORIZED BY THE REFERENCED RADIOACTIVE MATERIALS LICENSE(S) TO PERFORM THE PROCEDURES SPECIFIED ABOVE. I FURTHER BELIEVE THAT THE APPLICANT PHYSICIAN IS COMPETENT TO PERFORM THESE PROCEDURES INDEPENDENTLY. DATE

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement of representation to any department or agency of the United States as to any matter within its jurisdiction.

APPENDIX C

PERSONNEL TRAINING PROGRAM

1. Schedule for Training

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 your New York State license.

2. Description of the Training Program

Training will be sufficient to ensure that:

- a. Individuals who work in or frequent restricted areas are instructed in the terms specified in 10 NYCRR 16.13; and
- b. Individuals whose duties may require work in the immediate vicinity of radioactive materials are informed about radiation hazards and appropriate precautions.

3. Content of the Training Program

The program of instruction will include:

- a. Pertinent terms and conditions of the New York State 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 is used or stored.
- d. Potential hazards associated with radioactive material.
- e. Radiological safety procedures appropriate to the duties of the employee.
- f. Pertinent New York State regulations.

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- a. The obligation of all personnel to report unsafe conditions to the Radiation Safety Officer.
- b. 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 NYCRR 16.13.

4. Records that Document Training

Records of initial and refresher training will be maintained until New York State 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.

APPENDIX D

TOPICS THAT MAY BE INCLUDED IN OPERATING PROCEDURES

Good health physics practice dictates that you provide your personnel with operating procedures to give them clear and specific directions in their duties and responsibilities. These duties may include, but are not limited to, safety device checks, instrument calibration, monthly spot-checks, and leak tests. Operating procedures should not contain information that does not apply specifically to persons to whom they are directed. For example, housekeeping personnel would not follow the same procedures as therapy technologists.

The operating procedures should be designed for the program proposed in your application. Procedures should be complete and self-contained. Pertinent information contained in equipment manuals and other publications should be extracted and included in your operating procedures.

The following topics must be included in your operating procedures:

1. Receipt and Disposal of Radioactive Materials

Teletherapy licenses specify exactly the radioactive material by chemical and physical form (including manufacturer's name and model number) and the maximum activity that may be possessed and used in a specific teletherapy unit (manufacturer's name and model number). When radioactive materials are no longer needed, they may be transferred to a person or firm authorized to receive them.

Accordingly, operating procedures should be sufficient to ensure that radioactive materials received are within the limits specified in your license, that radioactive materials are transferred to appropriately licensed persons in accordance with the requirements of 10 NYCRR 16.8 and 16.111.

2. Use of the Teletherapy Unit

The operating procedures should specify who may operate the unit, how the unit may be used (e.g., in what orientations, for what purposes), and how the unit is to be operated (e.g., the sequence of steps to be followed to turn the beam on and off). The operating procedures should include instructions to ensure that only the patient is in the room when the primary beam is on and may specify certain daily checks of the unit to ensure its proper operation.

4. Personnel Dosimetry

Operating procedures should require teletherapy personnel to wear personnel monitoring devices (film or TLD badges); they should also contain instructions about the manner in which the devices should be worn, and about proper storage of the devices when they are not in use. If pocket dosimeters will also be used, frequent reading should be required. The operating procedures should contain directions to be followed in the event that a person receives or may have received a high exposure. In this case, the film badge or TLD of the affected person should be processed immediately.

5. Procedures for Securing the Teletherapy Unit

The operating procedures should specify the actions to be taken to ensure that the teletherapy unit is secure when unattended. Such actions should include locking the treatment room and the control panel, but may also include restricting access to the entire treatment area.

6. Instrument Calibration and Checks

Survey instruments must be calibrated in accordance with Appendix H to this Guide or equivalent procedures approved by the Department. They must be checked daily for proper operation using a check source.

The beam-on monitor must be checked daily for proper operation. The operating procedures should specify who is to make these checks and how they are to be made. If the beam-on monitor is malfunctioning, the licensee's operating procedures must specify alternative methods for determining beam status (e.g. survey meter).

Specify how and by whom dosimetry systems used for full calibration and spot-check measurements are to be calibrated and the frequency of calibration. Indicate the following:

- a) Full calibration measurements shall be performed using a dosimetry system that has been calibrated by one of the following two methods:

6. a. (1) The system must have been calibrated by the National Bureau of Standards or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or
 - (2) The system must have been calibrated within the previous four years: eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Bureau of Standards or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.
- b) Spot-check measurements shall be performed using a dosimetry system that has been calibrated by one of the following two methods:
- (1) The dosimetry system must have been calibrated in accordance to paragraph 6(a) above (and may be the same system used to meet the requirements of paragraph 6(a) above); or
 - (2) A dosimetry system used solely for spot-check measurements may be calibrated by direct comparison with a system that has been calibrated in accordance to paragraph 6(a) above. This alternative calibration method must have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

6. c) The licensee shall retain a record of each calibration, intercomparison and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section, the correction factor that was determined from the calibration or comparison, or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

7. Full Calibration of Teletherapy Units

Operating procedures should specify that only the Radiation Therapy Physicist named on the license will make full calibration measurements, and should describe the procedures to be followed and the instruments to be used. The calibration procedures must specify the following:

- a) Full calibration measurements on each teletherapy unit shall be performed:
- (1) Before the first medical use of the unit; and
 - (2) Before medical use under the following conditions: Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay; following replacement of the source or following reinstallation of the teletherapy unit in a new location; following repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - (3) At intervals not exceeding one year.
- b) Full calibration measurements must include determination of:
- (1) The output within + 3 percent for the several field sizes across the range of field sizes; several distances across the range of distances; and the beam modifying devices in use. Measurements shall be made with the dosimetry system described in paragraph 6(a) above.
 - (2) The coincidence of the radiation field and the field indicated by the light beam localizing device:
 - (3) The uniformity of the radiation field and its dependence on the orientation of the useful beam:

- (4) Timer constancy and linearity over the range of use;
 - (5) On-off error: and
 - (6) The accuracy of all distance measuring and localization devices in medical use.
- c) Full calibration measurements shall be made in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p. 213
- d) The outputs determined in paragraph 7(b) above shall be corrected mathematically for physical decay for intervals not exceeding one month.
- e) Full calibration measurements and physical decay corrections shall be performed by the radiation therapy physicist named on the license.
- f) Records of each full calibration shall be retained for the duration of use of the teletherapy unit source. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer linearity and constancy, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.
- g. Calibrations required by sub-paragraphs a)(1) and a)(2) of this section shall be confirmed by an independent check of either the dosimetry system used, or the output of the unit within 15 days of the calibration.

8. Periodic Spot Checks

A. Spot-Check Measurements of Teletherapy Units (Monthly)

The operating procedures should specify when, how, and by whom the spot-check measurements will be made. The spot-check procedures must specify the following:

- a) Spot-check measurements shall be performed once each calendar month on each teletherapy unit used for medical use and shall include determination of:
 - (1) Timer constancy, and timer linearity over the range of use;
 - (2) On-off error;
 - (3) The coincidence of the radiation field and the field indicated by the light beam localizing device;
 - (4) The accuracy of all distance measuring and localization devices used for medical use;
 - (5) The output for one typical set of operating conditions measured with the dosimetry system described in paragraph 6(b) above; and
 - (6) The difference between the measurement made in paragraph a(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at least full calibration corrected mathematically for physical decay).
- b) Spot-check measurement described in paragraph (a) of this section shall be performed in accordance with procedures established by a radiation therapy physicist qualified by training and experience as described in Section 4 of Appendix B of this Guide. That individual need not actually perform the spot-check measurements. However, the radiation therapy physicist shall review the result of each spot-check within 15 days and promptly notify the licensee of the results.

B. Safety Checks of Teletherapy Facilities (Monthly)

Safety checks shall be performed once each calendar month in each teletherapy facility to assure proper operation of:

- (1) Electrical interlocks at each teletherapy room entrance;
- (2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
- (3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;
- (4) Viewing systems;
- (5) Treatment room doors from inside and outside the treatment room; and;
- (6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

8. C. Follow-up and Records

- a) Arrangements will be made for prompt repair of any problem identified following the checks described in paragraphs 8A and 8B above. The teletherapy unit shall not be used following door interlock malfunction until the interlock system has been repaired.
- b) Records shall be retained of each spot-check and safety check described in paragraphs 8A and 8B above. The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

APPENDIX E - PART I

AMERICAN COLLEGE OF RADIOLOGY
FEBRUARY 1989
QUALITY ASSURANCE PROGRAM

The following is an outline for an ongoing quality assurance program. Its purpose is to objectively and systematically monitor and evaluate the quality and appropriateness of patient care delivered in the Radiation Oncology Department. Every effort will be made to identify problems, correct them and in this manner pursue the opportunities to improve patient care.

This program will be organized around the three principal areas of evaluation in Radiation Oncology which can be measured: structure, process and outcome. Structure includes the equipment and staff available to the treating facility. Process is concerned with the pretreatment evaluation and treatment prescription for patients; with the medical outcome stated in terms of control of tumor and evaluation of complications of therapy. Each of these factors interacts with the others in the typical situation. The program will include a monthly audit by a designated reviewer of an appropriate number of charts which have recently been completed. Following the audit of the charts with appropriate screens, all problems identified will be referred to the monthly meeting of the Radiation Oncology Quality Assurance Committee. A written report will be kept of all cases referred, and of the disposition of those cases. An ongoing record of problems identified will be maintained as well as a report on any special problem-oriented audits. A special report will be made of problems identified, solutions arrived at and the results of such solutions.

The Director of Radiation Oncology will be responsible for the institution and ongoing supervision of this program. It will be the responsibility of the Director to identify problems and when problems have been identified, see that actions are taken and the effectiveness of the actions evaluated.

STRUCTURE

It is mandatory that in a modern Radiation Oncology department, appropriate equipment and programs be in place to lend adequate structure for the performance of quality care. Equipment and programs are outlined below as the minimum requirement for such a department.

A. Equipment

1. **Supervoltage radiation therapy equipment for external beam therapy.** This must be an x-ray generator of 1 million volts or more, or a Cobalt-60 teletherapy unit. If the Cobalt-60 unit is the only megavoltage unit it must have a treatment distance of 80 cm or more.
2. **Electron beam therapy equipment or low energy x-ray equipment for the treatment of skin lesions and superficially placed lesions.**

3. Appropriate brachytherapy equipment for intracavitary and interstitial treatment.
4. Adequate physical measurement equipment to calibrate all treatment equipment in the department.
5. Access to, or presence of, computerized dosimetry equipment capable of providing external beam isodose curves as well as brachytherapy isodose curves.
6. Simulation equipment.
7. Special field shaping equipment, such as cerrobend casting.

B. Programs

1. Patient Protection Program
 - a. Charting systems for daily dose recording and summation.
 - b. Physics program for calibration of equipment that insures accurate field definition and accurate dose delivery to the patient.
 - c. A system for a "double check" of initial dose calculations within 48 hours.
 - d. A mechanical protection program to prevent mechanical injury by the machine or accessory equipment.
2. Personnel Protection Program
 - a. Film badge program.
 - b. Systematically inspected interlock systems.
 - c. Routine leak testing of all sealed sources.
 - d. Appropriate shielding equipment in situations where fluoroscopy is used.
 - e. Appropriate safety equipment for the use of sealed sources.
 - f. An education program in patient lifting and other safe work habits.
3. Educational Program
 - a. A continuing education program in the safe operation of all departmental equipment.

- b. A continuing education program in advanced treatment techniques and new developments in radiation oncology.
4. Regular maintenance and repair of equipment is required. The supervising physicist is responsible for documenting that any alteration in the maintenance and repair schedule does not affect the standards promulgated in this document.

C. Access and Environment

1. Ramps and doorways adequate for outpatient wheel chairs, walkers or ambulance litters.
2. Doors, halls, ramps, elevators adequate for hospital litters and hospital beds.
3. A safe and adequate environment including lighting, ventilation, heating, cooling and including appropriate rest areas.

D. Staffing

1. Staffing will in general be in accordance with the recommendations presented in the "Radiation Oncology in Integrated Cancer Management" report of the Intersociety Council for Radiation Oncology. This is commonly referred to as the "Blue Book." Exceptions to these recommended staffings may be made with justifications.

E. Access To Appropriate Supporting Facilities Including Diagnostic Laboratories and Imaging Facilities

PROCESS

The following items of process are considered mandatory and appropriate to patient care and are those elements of patient care which are measurable.

1. Confirmation of the presence of malignancy or a statement of benign condition.
2. Definition of tumor location and extent.
3. Definition of treatment volume.
4. Selection of dose.
5. Selection of treatment modality.

6. Selection of treatment technique.
7. Documentation of supervision of treatment and record of patient progress and tolerance.
8. Summary of completion with statement of follow-up plan.
9. Signed and witnessed consent required for all patients.

In addition to the above process, are those processes inherent in a recognized and acceptable physics quality assurance program as given below.

A. Process Methodology

1. A designated reviewer will audit an appropriate number of charts opened in each month after an adequate time to allow completion and closure of these charts.
2. These charts will be reviewed against a fifteen-point chart screen form attached.
3. Any charts failing to pass any one of the fifteen screens will be documented and referred to the Quality Assurance Committee for complete review, corrective action and inclusion in the ongoing process.

B. Quality Assurance Committee Process Review

1. The Director of the department will select appropriate personnel to constitute the Quality Assurance Committee.
2. The Quality Assurance Committee will meet on a regular basis to review the following items:
 - a. Results of the above review and audit process.
 - b. Review of the regular physics Quality Assurance Program Report.
 - c. Peer review reports from any other agency, committee or section of the Hospital which includes physicians in the Radiation Oncology Department.
 - d. Review of outcome studies from the Cancer Committee, Tumor Registry or any other section, department or committee of the Hospital which includes Radiation Oncology patients.
 - e. If there is not a separate mortality and morbidity conference then the Quality Assurance Committee will review the charts of any patient who dies during the

course of treatment, or any patient who has an unusual, severe or unexpected reaction to treatment. This may include individuals in which there is an unplanned interruption of treatment of more than 5 days.

- f. Review any case in which there is a "misadministration" or error in delivery of greater than 10% of the intended dose. This inclusion review of any chart in which mathematical corrections of 10% or more are made on the second check of dose calculations.
- g. A review of any chart in which an incident report is filed or in which there is report of an accident injury to a patient.

C. Individual Physician Appropriateness Utilization Review

- 1. If there is a Hospital wide or similar broad ranging peer review program which includes evaluation of appropriateness of actions by the Radiation Oncology physicians, this report will be reviewed by the Quality Assurance Committee and utilized as its physician appropriateness peer review.
- 2. If no such higher level program exists, a departmental physician peer review program will be put into place. This will consist of the random selection of an appropriate number of charts on an annual basis for each active practicing physician in the department. These charts will be reviewed by the Quality Assurance Committee as a whole for appropriateness of the prescribed treatment in light of the disease entity and patient status.

All of the above review mechanisms will be documented in writing as the minutes of the Quality Assurance Committee meetings. These minutes will be summarized on a quarterly basis and at a quarterly meeting there will be a review of the previous quarter's minutes. At that time any problems recognized will be analyzed and any special studies or further in-depth analysis required will be outlined and undertaken.

D. Other General Components That Help To Assure Quality

- 1. **New Patient Review Conference**
Review of the plan of management of all new patients by the complete attending staff. This is best done prior to initiating therapy. A record should be kept of cases presented and attendees present.

2. **Portal Film Review**
Review of all portal films by attending physicians other than the treating physician. This review may be included in a periodic chart rounds or a separate free standing meeting. A record should be kept of films reviewed, attendees present, important changes recommended and their resolution by the attending physician.
3. **Chart Rounds**
Periodic review of the records of all patients under treatment to assess completeness of the medical record and to evaluate and monitor their patients' progress. Records should be kept of the cases presented and the attendees present.
4. **Mortality and Morbidity Conference**
Review of deaths during treatment, unusual or severe, early or late complications of treatment and unusual post-treatment deaths. In addition, any untoward event occurring during treatment should be reviewed during this conference. Records should be kept of the cases presented, attendees present. The results of the analysis and the resolution of any problems that develop.

OUTCOME

It is important that all treating physicians follow patients to the greatest extent possible and document the outcome of therapy. This includes primarily an evaluation of the success of treatment in terms of tumor control and complications.

1. There is a requirement for semi-annual studies on an outcome basis to evaluate the results of the department's activities. If outcome studies are carried out on a Hospital-wide basis or by other larger units of the structure, such as major departments or the Cancer Committee, and the studies include a significant number of Radiation Oncology patients, then such reports will be reviewed by the Quality Assurance Committee and considered to have met the outcome study requirement.
2. If no such studies are performed outside of the Quality Assurance Committee then it will be necessary for the Committee to perform two annual outcome studies within the Radiation Oncology Department. These studies will be selected to meet the following requirements or criteria:

- a. Relatively common diseases for which Radiation Oncology treatment is frequently given.
- b. Diseases in which radiation therapy can be expected to have a significant effect on outcome.
- c. Diseases which can be followed within a reasonable period of time for evaluation of outcome.

Upon completion of the analysis of these disease entities by the Data Management Service, the results will be reviewed by the Quality Assurance Committee.

RADIATION ONCOLOGY

TREATMENT CHART SCREEN

- | NO | YES | | |
|-----|-----|-----|---|
| [] | [] | 1. | Is the diagnosis stated? |
| [] | [] | 2. | Is the stage of disease stated? |
| [] | [] | 3. | Is the pertinent histopathology report in the chart? |
| [] | [] | 4. | Is the relevant history of the disease stated? |
| [] | [] | 5. | Are the physical findings relevant to the disease stated? |
| [] | [] | 6. | Was a treatment plan or prescription dated and signed by the responsible physician at the beginning of treatment? |
| [] | [] | 7. | Was planned dose stated? |
| [] | [] | 8. | Was method of delivery stated? |
| [] | [] | 9. | Was treatment site or treatment volume stated? |
| [] | [] | 10. | Were fields documented by port films? |
| [] | [] | 11. | Are dosimetry calculations in the chart? |
| [] | [] | 12. | Is there a summary or a completion of therapy report? |
| [] | [] | 13. | Is there a follow-up plan stated? |
| [] | [] | 14. | Was the treatment record checked weekly by a designated reviewer? |
| [] | [] | 15. | Was there evidence of periodic examination of the patient by the responsible physician? |

APPENDIX E - PART 2

Basic Quality Assurance Program

Each facility must have a written Quality Assurance Manual. The manual should contain written policies and procedures for radiation protection and should fully describe the Quality Assurance Program. The manual should also describe procedures for achieving compliance with the following:

1. Ensuring that all elements of the evaluation and treatment of each patient are documented in the patient's record.
2. Ensuring that all prescriptions and other treatment records are legible and unambiguous. Staff shall be required to request clarification from the prescribing physician if any element of the prescription or other record is confusing, ambiguous or suspected of being erroneous.
3. Ensuring that discrepancies in records and observations (including those described in paragraph 2 above) are resolved before radiation therapy is administered to any patient if the discrepancy could result in a misadministration.
4. Ensuring that each patient undergoing treatment is evaluated on at least a weekly basis by a radiation therapy physician.
5. Ensuring that adequate records of evaluations of the patient's response to therapy are kept.
6. Ensuring that the treatment physician makes, dates, and signs a written prescription in the patient's chart or record that identifies the patient, the part of the body to be treated, the teletherapy unit to be used, the prescribed dose and the treatment plan. Any change in this prescription shall also be entered in writing in the patient's chart or record, and dated and signed by the treating physician.

In cases where an isodose distribution is generated, the treating physician shall also review, and approve by signature, the dose distribution that is represented by the isodose pattern.

The prescription shall also include daily and total doses to a specified site or isodose level in a definite overall time, the number of fields to be treated daily, and the number and schedule of all prescribed treatments. Additional information needed to describe the treatment protocol for each patient should also be included in the patient's treatment record. This may include: photographs; sketches; anatomical diagrams illustrating the location of treatment ports, blocks, etc.; and written descriptions of treatment fields and set-up information.

7. Ensuring that adequate treatment records containing data recorded at the time of each application of radiation are kept.

Treatment records should include the daily time or monitor unit settings, the daily and cumulative doses to the prescription point or isodose level, the daily dose delivered to each field, identifying number and dimensions of each field, consecutive number of the treatment, date of each treatment, identification of the teletherapy unit used, any treatment aids used, and the initials of the treating physician and the administering technologist.

8. Ensuring that before 20% of the prescribed dose has been delivered, teletherapy dose calculations are checked for accuracy as follows:

Manual dose calculations shall be checked by an individual who did not make the calculations, for errors in arithmetic, data transfer, and correct use of graphs and other data.

Computer-generated dose calculations shall be checked by an individual who did not enter the patient-specific data into the computer, to ensure that correct inputs for the patient were used in the calculations. This individual shall be familiar with the particular computer dosimetry system in use.

A weekly accuracy check shall be made of daily arithmetic operations in the patient's chart, by an individual who did not make the entries.

A physical measurement of the dose or dose-rate to be administered to a patient shall be made if:

- (a) a field size or distance that is outside the range of those measured in the last full calibration will be used; or
- (b) non-patient specific beam modifying devices which were not measured in the last full calibration will be used; or
- (c) patient-specific beam modifying devices such as compensators (other than blocks) will be used.

This measurement shall be made before 20% of the total prescribed dose has been administered.

If in the judgment of the prescribing physician, the delay caused by performing the dose verification described above would jeopardize the patient's health because of the emergent nature of the patient's condition, the verification may be done after treatment. The prescribing physician shall indicate this in his/her prescription and the verification shall be done as soon as possible.

9. A. Ensuring that the New York State Department of Health, Bureau of Environmental Radiation Protection, is notified of any teletherapy misadministration including:
- 1) the administration of radiation from a source other than the one intended; or
 - 2) radiation administered to the wrong patient; or
 - 3) the administration of radiation by a route of administration other than that intended by the prescribing physician; or
 - 4) the administration of radiation to a part of the patient's body other than that intended by the prescribing physician; or
 - 5) the administration of a therapy radiation dose such that errors in computation, calibration, time of exposure, treatment geometry, or equipment malfunction result in a total treatment dose differing from the final prescribed total treatment dose by more than + 10 percent; or
 - 6) the administration of a therapy radiation dose such that the dose administered in any individual treatment or fraction, differs from the prescribed dose for that individual treatment or fraction by more than + 50 percent.
- B. Ensuring notification of the referring physician of the affected patient, and the patient, of any misadministration listed in paragraphs A (1) through (5) above. Any misadministration listed in paragraph A (6) above will be evaluated by the Department, which will determine whether further notification is necessary.
- C. When it is not medically advisable to give such information to the patient, the information shall be made available to a qualified person on the patient's behalf. The notice to the patient or the person notified on the patient's behalf, must advise him or her of the patient's rights under Sections 17 and 18 of the Public Health Law.
- D. Ensuring that notifications are made within 24 hours after discovery of the misadministration. If the referring physician, patient, or the person to be notified on the patient's behalf, cannot be reached within 24 hours, they must be notified as soon as practicable. It is not required that the patient be notified without first consulting the referring physician; however, medical care for the patient must not be delayed because of this.

9. E. Ensuring that, within 15 days after an initial therapy misadministration report, the licensee shall send a written report to the New York State Department of Health, Bureau of Environmental Radiation Protection, containing the facility's name; a brief description of the event; the cause(s) of the misadministration; the patient's need for further medical follow-up or treatment; the action taken to prevent recurrence; whether the licensee notified the patient or a person on the patient's behalf; and what information was contained in that notice. The report to the Department must not include the patient's name or other information that could lead to identification of the patient.
10. Ensuring that a physics Quality Assurance Program is conducted under the supervision of the person named as the Radiation Therapy Physicist for the license. The program must be designed to ensure consistent and safe fulfillment of the dose prescription to the target volume, with minimal dose to normal tissue and minimal exposure to personnel. It should be conducted in accordance with accepted guidance, such as the American Association of Physicists in Medicine Report No. 13, "Physical Aspects of Quality Assurance in Radiation Therapy."
11. Auditing the Quality Assurance Program to assess its effectiveness and make any necessary modifications. At a minimum, programs should be audited annually by qualified individuals (i.e. radiation therapy physicists and radiation therapy physicians) who are not involved in the conduct of the licensee's therapy program.

APPENDIX F

EMERGENCY PROCEDURES FOR BEAM CONTROL FAILURE OR MALFUNCTION

If the light signals or beam-on monitor indicate 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 be 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 and Radiation Safety Officer at once.
7. Conspicuously post a sign in the area to warn others of the problem.

Radiation Therapist*

Phone No.: On Duty*

Off Duty*

Radiation Safety Officer*

Phone No.: On Duty*

Off Duty*

*Copies of emergency procedures posted at the teletherapy console will contain up-to-date information on the names and telephone numbers of personnel to be contacted.

APPENDIX G

TELE THERAPY SURVEY REPORTS

Teletherapy radiation surveys should be conducted by a person who is 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 and limitations of the radiation detection instrumentation and measuring devices that are used in the survey.

Contents of Survey Report

To fulfill the requirement for reporting the results of the radiation survey to the Department, the survey report should:

1. Provide the name, address, and license number of the person or organization that possesses the teletherapy unit and source.
2. Provide the name and address of each person conducting the survey.
3. Describe the reason for the survey (e.g., installation of a new source, relocation of the teletherapy unit).
4. Provide the date on which the work described in item 3 was completed.
5. Provide the date or dates on which the survey was conducted.
6. Provide the following information for each radiation detection instrument used for the measurements reported in items 10, 11, and 15 (or 16) of the survey report:
 - a. The manufacturer's name and model number:
 - b. The date of the last calibration before making these measurements; and
 - c. The standards (e.g., radionuclide, activity, and accuracy) and procedures used in the calibration.
7. Provide the manufacturer's name and the model name and number of the teletherapy unit.
8. Provide the manufacturer's name and model number of the teletherapy source.
9. Specify the activity of the source (in curies) and the corresponding assay date.

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10. Specify the intensity of the primary beam of radiation at a specified distance (e.g., roentgens per hour at a meter [RHM] or roentgens per minute at a meter [RMM]) as measured after the source has been installed in the protective source housing of the licensee's teletherapy unit and the date that this intensity was measured.
11. Provide the maximum and average radiation levels measured at 1 meter from the source in the off position. The average radiation level may be obtained by averaging measurements taken at 14 points on the surface of a sphere 1 meter in radius centered on the source; the diagram in Figure G-1 shows the location of the 14 primary points. Up to 26 points may be measured in accordance with NCRP Report No. 33. Describe the locations of the 14 to 26 points and the radiation levels measured at each of the points.
12. Describe the limits of beam orientation permitted by electrical or mechanical stops installed on the teletherapy unit. Specify each direction in which the teletherapy head can be moved and the maximum angle (from vertical) of the beam orientation in each direction. Also specify the angle orientation (e.g., 0 is vertical toward the floor; 90 is horizontal toward the east wall; 180 is vertical toward the ceiling; and 270 is horizontal toward the west wall). You may use sketches to describe the beam stops that limit the use of the primary beam. For units with an integral beam absorber, provide this information for orientations with the primary beam directed (a) toward the integral beam absorber and (b) away from the integral beam absorber.
13. For measurements of radiation levels in adjacent areas, which should be made during irradiation of a phantom at the normal treatment distance using maximum field size, describe:
 - a. The phantom used, including the material of which it is made and its size;
 - b. The source-to-phantom distance; and
 - c. The field size (field size should be the maximum permitted by the collimators unless physical means are used to restrict field size).
14. Submit plan and elevation drawings or sketches of the teletherapy facility: a scale of 1/4 inch = 1 foot is recommended. The drawings or sketches should:
 - a. Indicate the direction of north;

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14.
 - b. Show the location of the teletherapy unit and source within the treatment room:
 - c. Identify each area adjacent to the treatment room (including above and below):
 - d. Indicate the directions of primary beam usage and, in the case of an isocentric unit, the plane of rotation: and
 - e. Identify the locations at which radiation levels were measured (see items 15 and 16 below).
15. Rotational Units
 - a. For the primary beam directed toward the integral beam absorber, determine the rotational position of the teletherapy unit that causes the maximum radiation level in each area adjacent to the treatment room (including above and below the treatment room). Report the maximum levels measured with a phantom in the primary beam and specify the corresponding rotational position (e.g., angulation toward each area). In general, the maximum levels will be encountered with the beam oriented 30° from the perpendicular to the barrier in question.
 - b. For the primary beam directed away from the integral beam absorber and for units without an integral beam absorber, report the maximum radiation levels that are measured in each area adjacent to the treatment room (including above and below) and specify the orientation (e.g., angulation toward each area) that produces these maximum levels. Radiation measurements should be made with a phantom in the primary beam and the beam in its most adverse orientation with respect to each barrier. In general, measurements should be made at the maximum limits permitted by the beam stops.
16. For vertical units, report the maximum radiation levels measured in each area adjacent to the treatment room (including above and below) and specify the orientations (e.g., angulation toward each area) that produce the maximum radiation levels. Radiation measurements should be made with a phantom in the primary beam and with the beam in its most adverse orientation with respect to each barrier. In general, measurements should be made at the maximum limits permitted by the beam stops.
17. For each measured radiation level, explain how you are complying with 10 NYCRR 16.

18. Describe (1) the tests that were conducted; and (2) the results of these tests that ensure proper operation of the safety systems described below.

All tests should use a radiation detection instrument to confirm the "on-off" status of the source.

- a. Teletherapy treatment room door interlock system. The test should be sufficient to ensure that the door interlock system turns the primary beam of radiation off immediately upon opening of any door and that the primary beam cannot be turned on until all doors are closed and the beam "on-off" control is reset at the control panel.
 - b. Teletherapy "on-off" indicators, both mechanical and electrical (e.g., lights or mechanical indicator on protective source housing of teletherapy unit, over door to room, at console).
 - c. Electrical or mechanical stops installed to limit use of the primary beam of radiation. The tests should be sufficient to ensure that beam stops operate in the manner described in item 12.
 - d. Teletherapy treatment timing device. The tests should be sufficient to ensure timer constancy and linearity, that the source returns to the off position at the end of the preset time, and that the source does not return to the on position until the timer is reset.
19. If a teletherapy unit or source was removed, provide:
- a. The date of removal: and
 - b. The name, address, and license number of the person or firm who took possession of the unit or source.
20. If the surveyor recommends any changes to improve the safety of the operation of the teletherapy facility, describe the recommendations and your response to these recommendations.

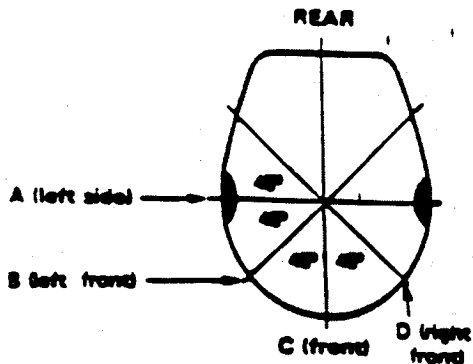


Figure G-1
TELETHERAPY HEAD SURVEY

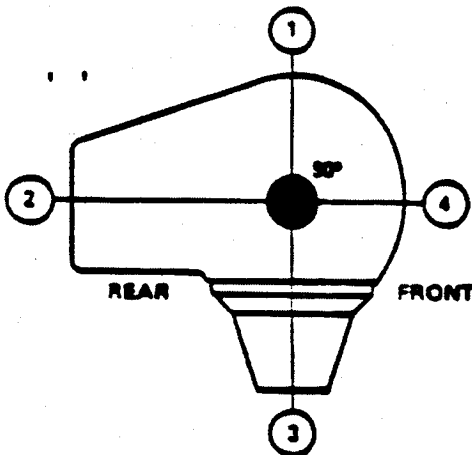
(Source in "OFF" position.
Measurements taken one meter
from source)

Top View-Showing
orientation
of Views A through D

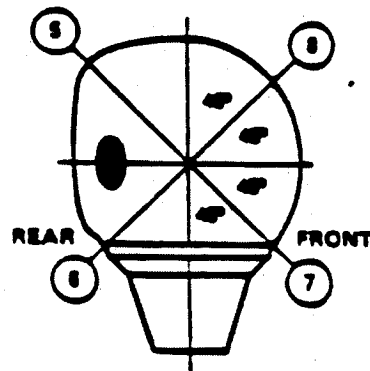
Position No.	Radiation Level (mR/hr)
View A	1 _____
	2 _____
	3 _____
	4 _____
View B	5 _____
	6 _____
	7 _____
	8 _____
View C	9 _____
	10 _____
View D	11 _____
	12 _____
	13 _____
	14 _____
Average value	_____
Maximum value	_____



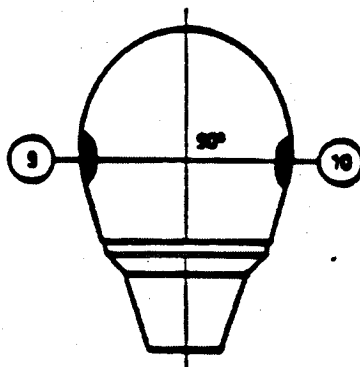
View A-Vertical
from left side



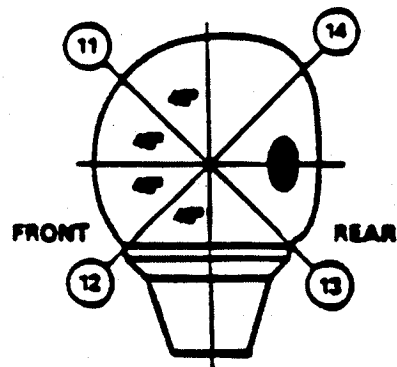
View B-Vertical
from left front



View C-Vertical
from front



View D-Vertical
from right front



Date of survey _____

Instrument used _____

Manufacturer's name & model number of teletherapy source _____

Date of installation _____

OUTPUT _____ RHM
 RMM

Date of output measurement _____



APPENDIX H

MODEL PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

You or your contractor may use the following procedure to calibrate survey instruments.

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing.")

Model Procedure

1. The source must be approximately a point source.
2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.
3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.
4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of cesium-137, 21 millicuries of cobalt-60, and 34 millicuries of radium-226.
5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.
6. A record must be made of each survey meter calibration.
7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.
8. The following three kinds of scales are frequently used on survey meters:
 - a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately $1/3$ and $2/3$ of full scale.
 - b. Meters that have a multi-decade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately $1/3$ and $2/3$ of the decade.

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8. c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be approximately 1/3 and 2/3 of the decade.
9. Readings above 1.000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.
10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.
11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:
 - a. The owner or user of the equipment;
 - b. A description of the instrument that includes manufacturer, model number, serial number, and type of detector.
 - c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;
 - d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
 - e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);
 - f. The angle between the radiation flux field and detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument.
 - g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;
 - h. The apparent exposure rate from the check source; and
 - i. The name of the person who performed the calibration, the date on which the calibration was performed and the license number (and issuing agency) of any contractor who performed the calibration.

12. The following information will be attached to the instrument as a calibration sticker or tag:
 - a. The source that was used to calibrate the instrument;
 - b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
 - c. For each scale or decade, one of the following as appropriate:
 - 1) The average correction factor,
 - 2) A graph or graphs from which the correction factor for each scale or decade may be deduced, or
 - 3) An indication that the scale was checked for function but not calibrated or, an indication that the scale was inoperative;
 - d. The angle between the radiation flux and the detector during the calibration; and
 - e. The apparent exposure rate from the check source.

Note: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

On the following page is a form you may want to use.



APPENDIX I

MODEL PROCEDURES FOR LEAK-TESTING

1. Each individual who will perform leak-tests on sealed sources or sources in devices will be provided with operating and emergency procedures, including:
 - a) Instructions for performing the wipe tests, including materials to use and methods of handling samples to prevent or minimize exposure to personnel.
 - b) Surveys to be performed, such as those around the housing to be sure the device is in the "safe", "store", or "off" position before wipe samples are taken from designated areas of the device. The survey meter used must have an audio function.
 - c) Surveys to be performed on leak-test samples to check for gross contamination.
 - d) Any specific instructions provided by source and device manufacturers on recommended methods and areas to be wiped.
 - e) Instructions on what to do in case of emergencies, for example, if sources or devices are found to be leaking or excessive radiation levels are found around devices. These instructions must include procedures for means of preventing and controlling the spread of contamination, and means of obtaining professional assistance, if needed.
2. The leak-test samples will be analyzed as follows:
 - a) If samples are analyzed in house, select a suitable detector that is sufficiently sensitive to detect 0.005 microcuries. Usually a well-type NaI(Tl) crystal with ratemeter is necessary to assay gamma-emitter leak-test wipes. To determine the efficiency of detection, a sealed source with the same radioisotope as the source being tested is used, and the source should have an activity between 0.1 and 10 microcuries. This activity will be certified by the manufacturer to an accuracy within a few percent.
 - b) If an outside service will analyze leak-test samples, this service must be performed by persons licensed to do so by the United State Nuclear Regulatory Commission or an Agreement State and a copy of this license will be kept on file with the leak-test results.