



Texas Department of State Health Services Radiation Safety Licensing Branch

Regulatory Guide 3.5

GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR THE USE OF TELETHERAPY DEVICES

I. Introduction

This guide describes the information the Department of State Health Services (DSHS) Radiation Control Program (Agency) staff requires to evaluate license applications for the use of high intensity gamma radiation sources in teletherapy devices for treatment of humans. The Agency normally issues a separate license for a facility's teletherapy program and issues another license to cover any other medical usage of radioactive material.

II. License Fees

An application fee is required for all licenses and must be submitted with any NEW application. The applicant should refer to Title 25 Texas Administrative Code (TAC) Section (§) 289.204 to determine the fee that should accompany the application. Review of the application will not begin until the proper fee is received by the Agency. The check or money order should be made payable to DSHS.

In the case of an application for renewal or amendment, a fee should NOT be submitted with the application. All current licensees will be billed according to the expiration month of their current license.

III. Instructions for Completing the Application

The application form used for nuclear medicine applications (RC Form 252-2a) is also used for teletherapy applications. The applicant should provide complete information to expedite the review of the license application. Two copies of the application should be submitted to the Agency, and a third copy should be retained, because the applicant will be bound by the statements made in the application once the license is issued.

Items 1 through 4 - Self-explanatory.

Regulatory Guides are issued to describe and make available acceptable methods of implementing specific sections of Title 25 Texas Administrative Code Chapter 289, Texas Regulations for Control of Radiation, to delineate techniques used by the staff in evaluating specific issues, or to provide guidance to applicants, licensees, or registrants. Regulatory Guides are NOT substitutes for regulations and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the Department of State Health Services, Radiation Control Program, to make necessary determinations to issue or continue a license or certificate of registration.

Comments and suggestions for improvements in these Regulatory Guides are encouraged at all times and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to the Department of State Health Services, Attn: Manager, Radioactive Material Licensing MC-2835, P.O. Box 149347, Austin, Texas 78714-9347.

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Item 5 - The individuals that are to use the teletherapy devices for treatment of humans must be physicians who are licensed by the Texas State Board of Medical Examiners. The using physicians must be therapeutic radiologists or therapeutic roentgenologists with three years experience in such specialty. Experience should include 200 hours of training in basic radioisotope handling techniques and three years of experience in clinical therapy with sealed sources. A preceptor statement (RC Form 252-2b) should be submitted to verify the training. Certification as described in 25 TAC §289.256(ff)(1)(G) will be accepted in lieu of a preceptor's statement.

Note: Applications for renewal of existing licenses need to include this information only for physicians who are to be added to the license.

Item 6 - The Radiation Safety Officer (RSO) is the person who will: be responsible for the radiation safety program; maintain the license and associated records; and be the primary contact with the Agency in administering the license. The RSO must have the authority to enforce radiation safety policy, suspend activities deemed unsafe, and require remedial action when necessary. The RSO is usually a medical physicist or one of the authorized users listed in Item 5.

Item 7 - Under "Additional Items Desired," complete as follows:

- (a) List radioactive isotopes, including any uranium to be used as shielding material.
- (b) Indicate "Sealed Source", source manufacturer, and the model number of the source to be installed.
- (c) Specify the maximum number of curies (not RHM) the source will have.
- (d) Specify the teletherapy unit manufacturer and model name and/or number.

(See Appendix B for sample form.)

Item 8 and 9 - Self-explanatory.

Item 10 -

- A. Facilities - Submit a plan drawing and front and side elevation drawings of the teletherapy room and a floor plan that shows the location of the room within the facility. Drawings should be to scale or sufficiently annotated to indicate thickness of barriers, type of barrier material, and the location of entrance ways, windows, conduits and other penetrations in the barrier material. The location of the teletherapy device inside the room and the distances from the source to adjacent areas outside the teletherapy room should also be indicated. Specify any restriction of beam orientation needed because of radiological protection requirements.

Indicate calculated maximum radiation levels in all accessible areas adjacent to, above, and below the teletherapy room on the drawings or on a supplementary sheet adequately keyed to the drawings. Occupancy factors should be discussed, determined, and assigned to each of these areas. (See NCRP Report No. 49.) Each area set apart as a "restricted area" must be indicated by the applicant. Any area that is not restricted must meet the criteria for an "unrestricted area".

Describe the method used to determine the shielding requirements for your facility

to meet these exposure requirements. Describe the results obtained based on workload, use factor, occupancy, and distance for each projection or source of radiation (primary, leakage, scatter) and each adjacent area. These results should be expressed in terms of the thickness required for each barrier material in each wall or direction. A comparison should be provided between these requirements and the actual barrier thicknesses as designed and/or installed.

Radiation levels in any "unrestricted area" shall not exceed two mrem in any one hour and the total dose to a non-radiation worker shall not exceed 100 mrem in any one year (25 TAC §289.202(n)). To ensure this, the applicant is responsible for periodically checking the occupancy of each area, making periodic radiation surveys, and keeping records of such surveys to demonstrate that no one will likely exceed the maximum permissible exposure values.

B. Radiation Protection Procedures - These procedures should include both the normal operating procedures and emergency procedures. The Radiation Protection Procedures should contain:

1. Duties of the RSO.
2. A description of person(s) authorized to use the unit for treatment, for research or calibration, and for maintenance purposes. A knowledgeable person must be present to supervise at all times when the beam is activated or when maintenance is performed.
3. Procedures for monitoring personnel exposure to radiation.
4. Procedures for testing the sealed sources for leakage every six months. If the leak tests will be analyzed at the facility, Regulatory Guide 5.1, "Guide for the Preparation of Leak Test Applications," may be obtained from the Agency.
5. Provisions for calibrating radiation survey instruments. (Regulatory Guide 5.2, "Guide for the Preparation of Survey Instrument Calibration Applications," may be obtained from the Agency.)
6. A method of securing the teletherapy unit when left unattended.
7. Instructions in case of a malfunction of the teletherapy unit or associated safety equipment. The instructions should include cessation of treatment until all malfunctions are corrected and the Agency is notified.
8. A schedule for conducting full calibration of the teletherapy unit, performing radiation surveys of the restricted and unrestricted areas, testing safety devices for proper operation, and for inspecting/servicing the teletherapy machine (see Appendix A).

C. Radiation Detection Instrumentation - In addition to radiation survey instrumentation, include a description of the beam-on room radiation monitor that will be used to independently indicate when the source is exposed by detecting scatter radiation. This monitor must operate correctly during a power failure.

D. Technicians - Describe the technician training, testing and supervisory program as indicated below.

1. Describe the minimum training technicians must have before they will be allowed to operate the machine. If training is not verified through recognized certification, describe the subjects, classroom hours of formal training and the supervised on-the-job experience to be required.
2. Indicate how performance will be gauged in the training program. Describe the tests and on-the-job performance evaluations that will be given to determine if the trainee has satisfactorily completed the educational program. Include the periodic training, testing, and evaluation that will be given thereafter.
3. Describe how the technicians will be supervised on the job. Specify how frequently the performance of technicians will be observed by a licensed user or the RSO to verify that established procedures are being followed. Confirm that an authorized user will be present any time that the source is exposed or when maintenance is performed on the device. Confirm that an authorized physician user and either the RSO or a licensed medical physicist will be present for therapeutic use of the device and that at least one of these individuals will be qualified/trained to operate the device.

E. Supplemental Data - In place of the Administrative Procedures specified in 10.E. of BRC Form 252-2a, the following supplemental data should be provided:

1. Give a description of the electrical interlocks, warning lights, or other devices used on all accessible entranceways to the treatment room. The treatment room must be equipped with interlocks that will cause the source shutter to close or source to retract immediately when any entrance door is opened. The interlocks must be connected so the source cannot be exposed until all entrance doors are closed and the teletherapy control reset at the console (25 TAC §289.256(dd)). It is recommended clearly visible warning lights indicating when the teletherapy beam is "on" or "off" be mounted near the entrances to the treatment room.
2. Include a description of the warning signs to be posted on or beside the entrance doors to the teletherapy room.
3. Enclose a copy of the emergency plan. A copy of the plan must be posted in a conspicuous place near the teletherapy control panel and all personnel involved should be instructed in the procedures. The emergency plan should describe action to be taken if an emergency arises, such as failure of the "on-off" mechanism, etc. The plan should include provisions for removal of the patient.
4. Give the name of the person who will load the source into the teletherapy head. Also, provide a discussion of the person's training and experience in handling radioisotopes, and the procedures for loading. The latter information may be omitted if the source is to be loaded by personnel from a company licensed to perform source exchanges.

5. Give the name of the person who will perform the full calibration of the teletherapy unit and who will conduct the teletherapy facility radiation surveys (see Appendix A). A resume of the individual's training and experience should be included if not previously submitted.
6. Provide a description of the system to be used to continuously view and communicate with the patient. If television is used, specify that treatment shall cease when the television is inoperative and no back-up system is available.
7. Describe area security safeguards and the method of controlling occupancy of all restricted areas.
8. Describe the system used to restrict the direction of the teletherapy unit's primary beam. Electrical, mechanical or physical means, rather than administrative means, must be used.
9. Describe the instructions and training to be given to ancillary personnel who will work in the vicinity of the teletherapy unit, e.g. clerical, nursing, security, house-keeping personnel.

F. Certification of Using Physicians - Self-explanatory.

Item 11 - The application must be signed and dated by the applicant or an individual duly authorized by the applicant to act for or on the applicant's behalf. Unsigned and undated applications will not be reviewed and will be returned to the applicant.

Pages 3 and 4 - Pages 3 and 4, the preceptor statement, is discussed under Item 5 of the application.

Appendix A

REQUIREMENTS AFTER LICENSURE

After the license is issued, the licensee is required to comply with the conditions of the license and 25 TAC §289.

- A. Calibration of Teletherapy Device - A calibration of the radiation output of the source and timing device shall be made after the installation of each teletherapy source and prior to the initiation of a therapy program. The calibration shall include measurements of the source output at a given distance from the source on a specified date for each of the normally used treatment fields, and a comparison of various timer settings to actual beam-on time. A report of the calibration should be retained by the RSO. Spot checks of source output should be made periodically thereafter.
- B. Radiation Surveys - Prior to initiation of a treatment program, and after each exchange of a teletherapy source, a radiation survey shall be made of:
 1. The teletherapy source housing, with the teletherapy source in the "off" position. The radiation levels at one meter from the teletherapy source in the "off" position shall not exceed a maximum of ten milliroentgens per hour.
 2. All areas adjacent to the treatment room, with the teletherapy source in the "on" position. The survey shall be performed with a phantom in the primary beam of radiation and shall clearly establish:
 - (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 25 TAC §289.202(f).
 - (b) That radiation levels in unrestricted areas do not exceed the limits specified in 25 TAC §289.202(n).
- C. Required Reports - A report of the survey results shall be sent to the Agency no later than 30 days after installation or exchange of a teletherapy source.
- D. Tests of Safety Devices - Prior to initiation of a treatment program and periodically thereafter, tests of safety devices should be made to determine proper operation of:
 1. Electrical interlocks on entrance doors to the teletherapy treatment room.
 2. The teletherapy source "on-off" indicators, both at the source housing and on the teletherapy machine control panel.
 3. Electrical or mechanical stops installed for the purpose of limiting the direction of the primary beam of radiation.
 4. The teletherapy treatment timing device.
 5. The radiation field room monitor, warning lights, safety switches, alarms, etc.

Appendix A (Continued)

REQUIREMENTS AFTER LICENSURE

- E. Inspection and Servicing - Each teletherapy machine shall be fully inspected and serviced during source replacement or at intervals not exceeding five years, whichever comes first, to assure proper functioning of the source exposure mechanism. This inspection and servicing must be performed by persons specifically authorized by the Agency, an Agreement State, or the U. S. Nuclear Regulatory Commission. A report of the inspection and servicing must be kept on file for inspection by the Agency.

The American National Standard Guidelines for Monitoring Cobalt-60 and Cesium-137 Teletherapy Equipment (ANSI-N449) outlines a recommended schedule for inspection and maintenance of teletherapy units. Attached is Table I from that document.

Table 1

Schedule of Periodic Inspection and Maintenance

Operation	Frequency (See Note)
Electrical and mechanical source-condition indicator check	Daily
Facility door interlock	Daily
Source holder/shutter movement check	Weekly
Source-surface distance (SSD)	Monthly
Spot-check measurements	Monthly
Timer	Monthly
Congruence of light and radiation fields	Monthly
Head movement	Semiannually
Stand and stretcher	Semiannually
Beam orientation	Semiannually
Central-axis indicators	Semiannually
Isocenter	Semiannually
Source leakage	Semiannually
Mercury shutter system	(See Note)
Pneumatic activating system	(See Note)
Electrical/mechanical source-condition indicator overhaul	(See Note)
Source holder/shutter assembly overhaul	(See Note)
Electrical system check and overhaul	(See Note)
Protective source housing, beam-off leakage	(See Note)
Full calibration	(See Note)

Note: All of the operations listed in this table shall be performed at the time of initial acceptance and also at the time of source change or other major maintenance. The operations marked (see Note) should all be performed with at a five-year interval as a maximum frequency. In addition, those indicated should be performed periodically at shorter intervals.