



Texas Department of State Health Services Radiation Safety Licensing Branch

Regulatory Guide 3.11

GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR THE USE OF REMOTE CONTROL BRACHYTHERAPY DEVICES

I. Introduction

This guide describes the information the Texas Department of State Health Services' (DSHS) Radiation Safety Licensing Branch (Branch) staff uses to evaluate license applications for the use of high, medium, and low dose rate gamma radiation sources in remote control brachytherapy (RCB) devices for treatment of humans. The guide is meant to provide only general guidance and should not be considered as containing all the information that might be required for a particular application.

II. License Fees

The applicant should refer to Title 25 Texas Administrative Code (TAC) Section (§) 289.204 to determine the fee that should accompany a new application. Review of the application will not begin until the proper fee is received by the Agency. This fee may be paid in cash, by money order, certified check, or personal check, made payable to the Texas Department of State Health Services. Do not submit a fee with renewal or amendment requests. If an amendment changes or adds a category of use or adds an additional authorized use site, the fee will be adjusted accordingly. The adjustments will be reflected on your next bill.

III. Completing The Application

The application form used for diagnostic nuclear medicine applications (BRC Form 41-2a) is also used for all types of therapy applications (i.e., nuclear medicine, teletherapy, brachytherapy). The applicant should provide complete information to expedite the review of the license application. Two copies of the application should be submitted. A third copy should be retained by the applicant because the applicant will be bound by the statements made in the application once the license is issued.

In accordance with 25 TAC §289.252(d)(5), all applications must be accompanied by a BRC Form 252-1 (Licensee Business Information Form). In conjunction with this requirement, 25 TAC §289.252(ii)(8) requires that all applicants provide certification of Financial Qualification by completing the bottom half of BRC Form 252-1.

Regulatory Guides are issued to assist applicants and licensees/registrants in developing operational procedures acceptable to the Department of State Health Services, Radiation Safety Licensing Branch (agency), that are compliant with specific sections of Title 25 Texas Administrative Code Chapter 289. Regulatory Guides are NOT substitutes for regulations and compliance with them is not required. Methods for compliance with regulations different from those set out in guides will be acceptable if they are considered by agency staff to provide for public health and safety and demonstrate compliance with regulations.

Comments and suggestions for improvements in Regulatory Guides are encouraged. Letters containing comments and suggestions should be sent to the Manager, Radiation Safety Licensing Branch, Department of State Health Services, 1100 W. 49th Street, Austin, Texas 78756-3189. Regulatory guides may be reproduced or may be obtained by contacting the agency at (512) 834-6688 or accessing the agency web page at www.dshs.state.tx.us/radiation

Items 1 through 4 - Self-explanatory.

Item 5 - The individuals who are to direct the use of RCB devices for treatment of humans must be physicians who are licensed by the Texas State Board of Medical Examiners. The authorized physician users must meet the training and experience requirements of 25 TAC §289.256(ff)(1)(G) and have obtained device-specific, manufacturer-provided training that includes standard clinical and emergency procedures. Applications for renewal of existing licenses must include this information only for physicians who are to be added to the license.

- a. Two of the following three persons must be present during patient treatment by HDR RCB: a licensed medical physicist with a specialty in therapeutic radiological physics and either the authorized physician user who is directing the treatment of the patient, or a physician under the supervision of an authorized user. One of the two must be qualified/trained to operate the HDR equipment and one of the two should be the authorized physician user.
- b. Any operator of HDR equipment must be able to provide documentation of the successful completion of manufacturer-provided training in routine clinical operation of the equipment as well as emergency procedures and active participation in the treatment of at least 5 cases of HDR RCB under the direct supervision of a person appropriately licensed to operate HDR RCB equipment.

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. Management must commit to delegating to the RSO the authority to enforce radiation safety policy, suspend activities determined to be unsafe, and require remedial action when necessary. The RSO is usually a medical physicist or an authorized user listed in Item 5 of the license. A list of the responsibilities for Radiation Safety Officers is located in 25 TAC §289.256(g)(1)(B).

Item 7 -

- a. List radioactive isotopes.
- b. Indicate the sealed source manufacturer(s) and the model number(s) of the sealed source(s) to be installed.
- c. Indicate the maximum number of sealed sources of each isotope to be possessed. Include the activity of each sealed source.
- d. Specify the RCB device manufacturer and model name and/or number.

For HDR units, you may wish to request two sources (or sets of sources); one (set) to be used in the device and one (set) to be stored in its shipping container, in your possession, for replacement of the source (set) in the irradiation device. This is generally not needed for Cs-137 or other LDR devices.

Items 8 through 9 - Self-explanatory.

Item 10 -

- a. Facilities - Submit sketches of the layout to include front and side elevation drawings of the therapy room(s). 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 use location of the device(s) inside the therapy room(s) and the distances from the source(s) to adjacent areas outside the treatment room(s) should also be indicated. Also, describe the placement of the console.

Indicate calculated maximum radiation levels in all accessible areas adjacent to, above and below the treatment room(s) directly on the drawings or on a supplementary sheet keyed to the drawings. If the location of the source will not be fixed by positive mechanical means, calculations should be based on source locations which produce the maximum exposure rate at a specified distance from each barrier. Occupancy factors should be discussed, determined, and assigned to each of these areas. [See "National Council on Radiation Protection (NCRP) Report No. 49".] Each area designated as a "restricted area" must be indicated by the applicant. Any area not restricted must meet the requirements for radiation levels in unrestricted areas in accordance with 25 TAC §289.202(n) (i.e., less than 2 mrem in any one hour and less than 100 mrem per year).

Describe the method used to determine the facility shielding necessary to meet exposure requirements. The method used should include maximum "on-time," use factors, and occupancy factors. The results of such determinations should be expressed in terms of the thickness required for each barrier material in each wall and/or direction. A comparison should be provided between the determined requirements and the actual barrier thicknesses as designed and installed.

- b. Radiation Safety Procedures - The procedures should include both standard operating and emergency procedures; and specifically contain:
 1. Duties of the RSO and the Radiation Safety Committee (RSC) (if established).
 2. A description of each individual's qualifications, other than the authorized physician users, who will operate the unit for treatment, research or calibration, perform source exchanges and/or perform minor maintenance. This should include documentation of each individual's general radiation safety training and experience with the specific device(s) to be operated. Please note that an authorized user must be present any time the source(s) are exposed or when maintenance is performed (the authorized physician user directing the treatment must be available whenever the sources are used for the medical treatment of humans).

3. Method and frequency of monitoring personnel exposure (film badges, TLD, etc.) Regulatory Guide 5.4, "Personnel Monitoring Services," lists authorized suppliers and is available from the Agency upon request.
 4. Describe how you will ensure that sealed sources are tested for leakage every six months. If sources will be exchanged more often, indicate such and that leak tests of new sources will be confirmed by the RSO. 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. Otherwise, a commitment to use a licensed vendor will suffice. If a vendor is used, the licensee is responsible for ensuring that the vendor's procedures meet the minimum requirements for leak testing of sealed sources included in Regulatory Guide 5.1.
 5. Confirm that you will obtain and use calibrated radiation survey instruments. Regulatory Guide 5.2, "Guide for the Preparation of Survey Instrument Calibration Applications," may be obtained from the Agency if in-house calibration is desired. Otherwise, a commitment to use a licensed vendor for calibration of survey instruments will suffice. If a vendor is used, the licensee is responsible for ensuring that the vendor's procedures meet the minimum requirements for instrument calibration included in Regulatory Guide 5.2.
 6. Written procedures for securing the therapy unit console and room when left unattended or when other use of the room is taking place. Confirm that copies of written procedures will be given to appropriate staff and state where it will be documented that all staff is familiar with those procedures, the license and applicable requirements of 25 TAC §289.
 7. Describe procedures, frequencies and equipment used to perform the full calibration measurements detailed in 256(dd)(8)(B).
 8. Confirm that the room does not have "blind spots" which might prevent the observation of persons in the room using routine methods of observation.
- C. Radiation Detection Instrumentation - Describe the radiation survey instruments and probes to be present when the machine is in use. Include make, model and ranges. In addition to radiation survey instrumentation, include a description of the "source(s) exposed" room radiation monitor that will be used to detect direct or scatter radiation and indicate when the source is exposed. This monitor must operate correctly during a power failure and be checked each day of use.

D. Technologists -

(For RCB applications, this section of the application will describe, instead the qualifications of personnel operating the equipment).

Describe the minimum training and experience of all operators of the RCB unit.

1. Describe the minimum radiation safety and machine training operators must have before they will be allowed to operate the device; include manufacturer-provided operator training. Describe the subjects, classroom hours of formal training, and the supervised on-the-job experience to be required. Provide name and affiliation of instructor(s) conducting the training.
2. Indicate how performance will be evaluated in the training program. Describe the on-the-job performance evaluations that will be given to determine that the operator can satisfactorily operate the unit under normal and emergency conditions. Include the frequency of periodic training, drills, and evaluations that will be given thereafter. Confirm that the retraining will include at least annual rehearsals of emergency procedures.
3. Describe how the operators will be supervised on the job. Specify how frequently the performance of operators will be observed by a licensed user and/or the RSO to verify that established procedures are being followed.

E. Administrative Procedures - The following supplemental data should be provided:

1. Give a description of the electrical interlocks, warning lights, alarms, or other devices used on all entrances to the treatment room. The treatment room must be equipped with interlocks that will cause the source(s) to retract into a shielded position immediately when an entrance door is opened. The interlocks must be connected so the source(s) cannot be exposed until all entrance doors are closed and the console is reset [25 TAC §289.256(dd)(5)]. It is recommended that clearly visible warning lights indicating when the beam is "on" or "off" be mounted near the entrance(s) to the treatment room.
2. Include a description of the warning signs to be posted on or beside the entrance door(s) to the therapy room and the explanatory signs to be placed on or beside the permanently installed radiation monitor.

3. Enclose a copy of the emergency instructions. A copy of this must be posted in a conspicuous place near the unit's control panel, and all personnel involved must be instructed and drilled on the procedures. The emergency instructions should describe actions to be taken in the event of any anticipated emergency, such as failure of the "on-off" mechanism, etc. The instructions should include provisions to retract the source from the patient, handle the source(s) remotely, secure the area, post a warning, and provide name(s) and telephone number(s) of person(s) to contact. Also, describe emergency response tools such as appropriate wire cutters and a shielded container large enough to accommodate any apparatus used to hold the source.
 4. Provide a description of the system to continuously view and communicate with the patient. If television is to be used, confirm that treatment shall cease when the television is inoperative and no back-up system is available.
 5. Describe area security safeguards and the method of controlling occupancy to all restricted areas.
 6. Any therapy room containing more than one therapy device or machine must be provided with administrative and physical controls for preventing the activation of the device(s). Describe the positive mechanical or electrical means for preventing the activation of more than one device. Include the instructions needed to implement these means and to verify that the correct unit has been selected for use. Attaching both keys to a single ring will suffice for this purpose.
 7. Describe the instructions and training to be given to ancillary personnel who will work in the vicinity of the unit, e.g. clerical, nursing, security, and housekeeping personnel. This may be simply additional hazard communication training to be incorporated into an existing training program.
- F. Certification of Using Physicians - Signed statements should be obtained from any individuals to be authorized to use the devices which certify that they have read, understand and agree to abide by all the conditions of the radioactive material license as well as the operation, safety and emergency procedures manual (as amended) which was reviewed and approved by the Agency in conjunction with the issuance of the license.

Item 11 - The application must be signed and dated by the applicant (CEO [President/Administrator]) 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.