



Texas Department of State Health Services Radiation Safety Licensing Branch

REGULATORY GUIDE 3.6

GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR THE USE OF MEDICAL EYE APPLICATORS

I. Introduction

This guide describes the information the Department of State Health Services (DSHS or Agency) staff needs to evaluate a radioactive material license application for the use of a medical eye applicator.

II. License Fees

An application fee is required for all specific 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 amount of 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 the Texas Department of State Health Services.

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. Issuance of Licenses

Licenses are issued in the name of the legal entity seeking authorization to possess and use the eye applicator after the Agency determines the entity has satisfied all requirements for licensure.

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, Department of State Health Services, Attn: Manager: Radioactive Material Licensing MC-2835, P.O. Box 149347, Austin, Texas 78714-9347. 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

IV. Requirements

Complete the application, BRC Form 252-2a, in sufficient detail to allow the Agency to make a realistic review of the applicant's radiation protection program. Specific items of the application are discussed below.

Items 1 through 4 - Self explanatory.

Item 5 - Acceptable training and experience for a using physician is specified in the Appendix. The preceptor must verify the training by completing and signing the preceptor statement (RC Form 252-2b), unless the physician was previously listed on a radioactive material license for use of a medical eye applicator. If a Nuclear Regulatory Commission (NRC) or Agreement State license, provide a copy of the license. In the case of a Texas license, reference the license number rather than submitting a preceptor statement.

Item 6 - The Radiation Safety Officer (RSO) is designated to be responsible for the radiation safety program. The RSO maintains records of use, leak tests, and other required records and is the primary contact with the Agency concerning matters of licensure. The physician may serve as RSO.

Item 7 - Under "Additional Items Desired," top of page two, complete as follows.

- (a) List the isotope(s), such as "Sr-90".
- (b) List the manufacturer and model, such as "Tracerlab R-1".
- (c) List the activity, such as "100 mCi".
- (d) List the uses, such as "Treatment of superficial eye conditions in humans", or "in animals", as appropriate.

Items 8 and 9 - Self explanatory.

Item 10 - Provide separately the information outlined in the Appendix.

Item 11 - Include a description of the facility where the applicator will be stored including a sketch of the room, the storage location within the room, and the location of caution signs. Describe any shielding used and how the applicator will be secured against loss, theft, or unauthorized use.

Item 12 - Procedures should include statements concerning the following items.

1. Where the applicator will be used and who will be authorized to use it.

2. Method of testing the applicator source for leakage every six months. If a commercial kit is used, state the name of the company supplying the kit.
3. Procedures for cleaning or sterilizing the applicator that minimize the radiation exposure to the person performing this operation.

NOTE: Employees handling the applicator must be provided with appropriate personnel monitoring devices (e.g., finger and/or whole body badges).

Item 13 - Although a survey instrument is not required, a radiation survey must be made of the storage facility with the applicator present (25 TAC §289.202(p)) and a record kept of the radiation level on the surface of the storage facility and at one foot from the surface. Once this storage survey is made and documented, no further surveys are required unless storage condition change or additional sources are obtained. A confirmatory statement must be provided that a radiation survey will be made within 30 days after the source is obtained. (This will be verified at the first inspection by the Agency.)

Item 14 - Self-explanatory. In most cases, Financial Qualification can be established via self-attestation on BRC Form 252-1, Business Information Form.

Item 15 - The application must be signed and dated by the applicant or an individual duly authorized by the applicant to act on the applicant's behalf. Unsigned and undated applications will not be reviewed and will be returned to the applicant. Retain one copy for your files and mail two copies of the license applications and appropriate fee to:

Texas Department of State Health Services
Radioactive Material Licensing MC-2003
Medical and Academic Licensing Program
P.O. Box 149347
Austin, Texas 78714-9347

Appendix

ACCEPTABLE TRAINING AND EXPERIENCE FOR THE USE OF A SR-90 MEDICAL APPLICATOR IN THE TREATMENT OF SUPERFICIAL EYE DISEASES

- A. Active practice in therapeutic radiology or ophthalmology.
- B. Training in basic radioisotope handling techniques applicable to the use of a Sr-90 medical eye applicator (24 hours) as described below.
 - 1. Basic radiation physics and instrumentation. (6 hours)
 - 2. Principles of radiation protection and safety. (6 hours)
 - 3. Mathematical calculations basic to the use of radioactive material. (4 hours)
 - 4. Biological effects of radiation. (8 hours)
- C. Clinical training and active participation in the treatment of at least five patients with the Sr-90 medical eye applicator. This clinical training must be under the supervision of a preceptor and should include examination of patients, determination of the suitability of using the applicator in the treatments, actual treatment of superficial eye conditions, calculation of the radiation doses, management of the patient, and discussion with the preceptor of case histories. The preceptor must verify the training by completing and signing the preceptor statement (RC Form 252-2b).

Alternative

Evidence of certification as described in 25 TAC §289.256(ff)(1)(E) may be submitted in lieu of the information requested in B. and C. above.