Radioactive Material License Guide

Eye Applicator

Louisiana Department of Environmental Quality
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INSTRUCTIONS AND LICENSING GUIDE

Eye Applicator

A. Any section of the application which is not applicable should be so designated.

B. Material submitted on a separate attachment should be clearly identified: For example, Attachment A, Page 5, Item C.

LICENSE FEES:

A fee is required for all initial applications and licenses that are required to be reissued. The applicant should refer to the Department's fee schedule to determine the amount of the fee that must accompany the application. Review of the application will not begin until the Department receives the proper fee. If you have any questions concerning the fee or the amount to submit, please do not hesitate to contact Department. A fee is not required for license renewals.

FILING AN APPLICATION:

A license application for radioactive material should be submitted on Form DRC-11, Application for Radioactive Material License and Form DRC-13. The applicant should complete all items on the application form delineated in this licensing guide.

Submit one copy of the application and all attachments to the Department. The applicant should retain one copy, since the license will require as a condition that the institution follow the statements and representations set forth in the application and any supplements following.

Since the space on Form DRC-11 may not be sufficient to contain all of the required information, additional sheets should be attached. Each separate sheet or document submitted with the application should be identified by heading indicating the appropriate item number. When completed, Form DRC-11 should be signed and dated by a representative of the institution's management.

ALARA PROGRAM

Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with LAC 33:XV.406.

To satisfy this requirement:

1. the management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations; or

2. for licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or by management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology and the cost of improvements in relation to benefits.

The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

1. A commitment by management to keep occupational doses as low as reasonably achievable;

2. a requirement that the radiation safety officer brief management once each year on the radiation safety program;

3. personnel exposure investigational levels that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce or eliminate the probability of recurrence.

Please submit a copy of your ALARA program for the Department's review.

FORM DRC-11

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE

Item 1 - Enter the name of the firm applying for the license, the mailing address, telephone number, fax number, and email address.

Item 2 - Check New application or Renewal application box.

Item 3 - If the mailing address in Item 1 is a P. O. Box, or if different from the location where the radioactive material is located, then enter the street address where the material will be located or other descriptive address (such as 5 miles east on Highway 10, Anytown, Louisiana) to allow the Department to easily locate your facility.

Item 4 - Radiation Program Personnel:

A qualified physician must be designated the responsibility for radiation protection. The individual physicians who would use or supervise use of radioactive materials should be listed and the qualifications and training of these individuals entered on the back of Form DRC-13 or on a separate attachment.

Item 5 - Personnel Monitoring:

To determine compliance with the occupational dose limits of LAC 33:XV.410, licensees may be required to monitor external and internal occupational dose. Monitoring of external dose will be required if individuals are likely to receive in one year a dose in excess of 10% of the occupational dose limits for adults. Monitoring of internal dose will be required if individuals are likely to receive in one year an intake in excess of 10% of the applicable annual limit on intake. Please submit your criteria for determining if personnel monitoring is necessary or not. If it is necessary, please complete the information in Item 5.

Item 6 - Area Monitoring:

Parts A, B and C should be marked not applicable.

Item 7 - Leak Tests:

The source must be tested for leakage and/or contamination at least every six months. Submit the name of the individual or company who will perform this service for you. If the applicant plans to perform the leak tests, supply detailed procedures, including instrumentation, required calibration sources, and sample calculations.

Item 8 - Waste Disposal:

This column may be marked not applicable, although it should be recognized by the licensee that Strontium 90 sources for eye applicators may only be returned to a firm or person holding a specific license for receipt or disposal of such devices.

Item 9a - Health Physics Program

Information for this item should be provided in the form of a very short narrative which describes how the use of Strontium 90 eye applicator will be controlled to prevent unsupervised use and what policies govern the use of the applicator at your facility. If the Strontium 90 eye applicator is to be transported to other institutions and if it is to remain at these institutions longer than the period of immediate use, state how access to the radioactive material is controlled.

Quality Management Program

This section is applicable for any licensee administering: any teletherapy radiation dose; any gamma sterotactic radiosurgery radiation dose; any brachytherapy radiation dose; any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; or any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131. Each applicant shall submit to the Department a quality management program as part of the application for a license and implement the program upon issuance of the license by the Department. Please refer to LAC 33:XV.777 for guidance. The submitted Quality Management Plan should include written policies and procedures that meet the following five objectives:

1. That prior to administration, a written directive, signed and dated by an authorized user, is prepared for each applicable administration. (A written directive for Sr-90 eye applicators means an order, in writing, for a specific patient, dated and signed by an authorized user, prior to administration of radiation. It must include the radioisotope, the treatment site, source strength (corrected for decay) and exposure time (or equivalently, the total dose).

2. That prior to each administration, the patient is identified by more than one method as the individual named in the written directive.

3. That final plans of treatment and related calculations are in accordance with the respective written directive.

4. That each administration is in accordance with the written directive.

5. That any unintended deviation from the written directive is identified and evaluated, and appropriate action taken.

Item 9b - Physical Facilities:

Describe briefly the area in which the eye applicator is stored at your office and how the location is labeled.

Item 10 - Health Physics Instrumentation:

Not applicable.

Item 11 - General Instrumentation:

Not applicable.

Item 12 - Medical Supplements

This section may be marked not applicable if the Strontium 90 eye applicator is only to be used at your office. If the eye applicator is to be used at other institutions such as hospitals, then the names of these hospitals should be stated in this section and their approval letters should also be referenced and submitted with the application.

Calibration and Decay Correction

Please submit your procedures for calibration and decay correction of the Sr-90 eye applicator. The source output or activity must be determined using a dosimetry system calibrated using a system or source traceable to National Institute of Science and Technology (NIST) and published protocols currently accepted by nationally recognized bodies. Please note that in accordance with the current standards, only an authorized medical physicist can calculate the activity of each Sr-90 source that is used to determine treatment times for ophthalmic treatments.

ADDENDUM TO PERMIT APPLICATIONS:

The "ADDENDUM TO PERMIT APPLICATIONS PER LAC 33:I.1701. This form must be completed before a license can be issued. This form can be found at http://www.deq.louisiana.gov/portal/tabid/240/Default.aspx

FORM DRC-13

Sealed Sources:

The applicator should be identified as to manufacturer, model number and strength, and the qualification of each user should be summarized on the back.

Radiological Qualifications and Training:

Please provide the qualifications of all physicians who will use the applicator. Please refer to LAC 33:XV.763.G (Appendix A) for training requirements.

IT Questions

Part of the application for a radioactive material license must include response to the "IT Questions. " The "IT Questions" were formulated by the Supreme Court in the Save Ourselves vs. Louisiana Environmental Control Commission, 452 So. 2d 1152 (La. 1984). The responses are intended to assure the Department that the activity and the site are suitable. If not applicable, please indicate N/A. The five questions are:

A. Have the potential and real adverse environmental effects of the proposed facility been avoided to the maximum extent possible?

B. Does a cost-benefit analysis of the environmental impact costs balanced against the social and economic benefits of the proposed facility demonstrate that the latter outweighs the former?

C. Are there alternative projects which would offer more protection to the environment than the proposed facility without unduly curtailing non-environmental benefits?

D. Are there alternative sites which would offer more protection to the environment than the proposed facility without unduly curtailing non-environmental benefits?

E. Are there mitigating measures which would offer more protection to the environment than the facility as proposed without unduly curtailing non-environmental benefits?

APPENDIX A

Training for Ophthalmic Use of Strontium-90

Except as provided in LAC 33:XV.773, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

1. is certified in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

2. is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

    A. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

        (1) radiation physics and instrumentation;

        (2) radiation protection;

        (3) mathematics pertaining to the use and measurement of radioactivity; and

        (4) radiation biology.

    B. To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

        (1) examination of each individual to be treated;

        (2) calculation of the dose to be administered;

        (3) administration of the dose; and

        (4) follow-up and review of each individual's case history.