



## **Radioactive Material License Guide**

### **IN VITRO**

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# RADIOACTIVE MATERIAL LICENSE APPLICATION

## INSTRUCTIONS AND LICENSING GUIDE

### In-Vitro Procedures

This guide describes the type and extent of information needed by the Department staff to evaluate an application for a specific license for the possession and use of radioactive material. This type of license is provided for under LAC 33:XV.325. The applicant should carefully study the regulations and this guide and submit all information requested. Please remember that any necessary information that is not submitted will delay completion of the review of your application.

The Department usually issues a single radioactive material license to cover an institution's entire radioisotope program. Separate licenses are not normally issued to different departments of a medical institution, nor are they issued to individuals associated with the institution. If the institution for which you are making application has a license for nuclear medicine then an additional license for in-vitro studies will probably not be necessary. Contact the individual responsible for the nuclear medicine license to see if the studies you are requesting are presently authorized by the existing license. If so, you may need only to be added as an authorized user.

If your facility decides that an additional license is needed for the in-vitro studies, the following Louisiana Radiation Regulations are applicable and should be used in conjunction with this guide. The applicant should carefully study the regulations since this guide does not substitute for understanding the requirements of the regulations.

- A. Chapter 1, General Provisions
- B. Chapter 3, Licensing of Radioactive Material
- C. Chapter 4, Standards for Protection Against Radiation
- D. Chapter 10, Notices, Instructions and Reports to Workers, Inspections

## LICENSE FEES:

A fee is required for all initial applications and for licenses that are required to be reissued. The applicant should refer to LAC 33:XV. Chapter 25 to determine the amount of the fee that must accompany the application. Review of the application will not begin until the proper fee is received by the Department. If you have any questions concerning the fee or the amount to submit, please do not hesitate to contact the Department.

## 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.

## DRC-11

### Application for a Radioactive Material License

- ITEM 1 - Enter the name of the applicant, the telephone number and mailing address to which correspondence should be directed. The applicant should be the name of the hospital, laboratory or clinic and not an individual's name. A physician may be named as the applicant only if he is requesting use of radioactive material at his private office.
- ITEM 2 - Indicate whether this is an application for a license, an amendment, or a renewal.
- ITEM 3 - If the mailing address in Item 1 is a P. O. Box or if different from the location where radioisotopes will be used and/or stored, then enter the street address where radioisotopes will be primarily used. If appropriate, specify the department or location within the institution where radioisotopes will be used.
- ITEM 4 - List only those individuals who will be primarily using the radioisotopes.

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 6a - Contamination Surveys

Please describe your procedures for performing contamination studies. Laboratory areas where only small quantities, less than 200 microcuries of radioactive material, are used may be surveyed weekly and results recorded weekly. However, as a good laboratory QC practice, it is recommended that the laboratory be surveyed daily with use. Contamination surveys for this purpose can be easily accomplished by using a simple filter paper smear test. Results of the smear test may be obtained by taking the paper smear and evaluating it with the same instrument used for in-vitro procedures. If results of the smear test indicate any contamination, the area should be decontaminated with detergent and water. Another smear test should be performed after the area has been cleaned to assure adequate decontamination. As a practical rule for establishing whether an area is contaminated or not, any smear test revealing readings greater than 2 times background should be considered as adequate evidence of contamination and the decontamination procedure performed. Background may be established by counting a filter paper that has not been used to perform the smear test. Results of this test should be recorded in units of activity; however, disintegrations per minute are acceptable.

ITEM 6b - Radiation Area Surveys

Radiation area surveys are not required in laboratories where only in-vitro procedures are performed.

ITEM 7 - Not applicable.

ITEM 8 - Waste Disposal

LAC 33:XV.464, Disposal of Specific Waste, allows a licensee to dispose of hydrogen 3 or carbon-14 without regard to its radioactivity if the concentration is less than 0.05 microcuries per gram of medium used for

scintillation counting. For I-125, please refer to LAC 33:XV.462 regarding disposal by release into sanitary sewerage.

ITEM 9a - Health Physics Program:

Written radiation safety procedures should be provided. These should include:

1. Procedures for receiving packages containing radioactive materials during off-duty hours, and for notification of responsible persons upon receipt of radioactive materials. These procedures should be adequate to ensure that radioactive materials are secured against unauthorized removal at all times.
2. Procedures for Opening packages. The following model procedure is recommended:
  - a. Open packages in a restricted area.
  - b. Put on gloves to prevent hand contamination.
  - c. Visually inspect the package for any sign of damage (e.g., wet or crushed).
  - d. Open the package with the following precautionary steps:
    - 1) Remove the packing slip.
    - 2) Open the outer package following the supplier's instructions, if provided.
    - 3) Open the inner package and verify that the contents agree with the packing slip.
    - 4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
  - e. If there is evidence of leakage, wipe test empty packages for contamination before discarding.
3. Provide a copy of your laboratory instructions. Typical instructions should include:
  - a. Wear laboratory coats or other protective clothing at all times in

areas where radioactive materials are used.

- b. Wear disposable gloves at all times while handling radioactive materials.
  - c. Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.
  - d. Do not store food, drink, or personnel effects in areas where radioactive material is stored or used.
  - e. Never pipette by mouth.
  - f. Wipe test radioactive material storage, preparation and use areas weekly from contamination.
  - g. Refrigerators shall not be used jointly for foods and radioactive materials.
  - h. Secure all radioactive material when not under the constant surveillance and immediate control of the authorized users.
4. Emergency procedures you will follow in case of spills or other types of accidents involving radioactive materials.

ITEM 9b - Physical Facilities

Please furnish the Department with a diagram of the lab which includes adjacent areas, receipt areas, waste, storage areas, etc.

ITEM 10 - Not applicable.

ITEM 11 - General Instrumentation

List only those instruments that are used for in-vitro procedures.

Be sure to enter the date of the application, the name of the applicant, and the signature and title of the individual who will be supervising the use of radioactive material.

Form DRC-13

Schedule of Radioactive Materials. Please complete this section and include the isotopes, activity, etc. that you wished to be licensed for.

Radiological Qualifications and Training. List the individuals and training for personnel working with the radionuclides.

IT QUESTIONS

This section is required to be addressed. If not applicable, please mark N/A.

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. Also include the Addendum to Permit Application per LAC 33:I.1701 which can be found at: <http://www.deq.louisiana.gov/portal/tabid/240/Default.aspx>

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