Radioactive Material License Guide

Laboratory Analysis

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LABORATORY ANALYSIS

INTRODUCTION:

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 Section 325 of the Louisiana Radiation Regulations. 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 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. Radiation Protection fee schedule 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 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 Section 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 direct-ed.

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. Describe the extent of use and the facilities and equipment at each location.

ITEM 4 - List only those individuals who will be primarily using the radioisotopes. Specify the name of the person who will be designated as the radiation protection officer. This person should be responsible for implementing the radiation safety program and therefore readily available to the users in case of difficulty and should be trained and experienced in radiation protection and in the use and handling of radioactive materials.

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.

The applicant should show that the need for bioassays has been thoroughly considered and should establish the adequacy of the proposed bioassay program in relation to the proposed program of use of radioactive material. Bioassays are normally required when individuals work with millicurie quantities of H-3, I-125, or I-131 depending on the type of work, equipment and procedures. Other materials may also be used in physical or chemical forms and under conditions that present an opportunity for uptake by the body through ingestion, inhalation, or absorption. A bioassay program to determine and control the uptake of radioactive material should be

considered and discussed in relation to each such material and procedure.

The criteria to be used in determining the need for bioassays, the type and frequency of bioassays that will be performed, and the bioassay procedures should be specified and described in detail. If a commercial bioassay service is to be used, the name and address of the firm should be provided.

Bioassays may not be substituted for other elements of a safety program such as air monitoring and dispersion control (hoods, glove boxes, etc.) and for well-thought-out and well-executed handling procedures.

ITEM 6a and 6b - Contamination Surveys and Area Surveys:

A survey should include the evaluation of external exposure to personnel, concentrations of airborne radioactive material in the facility, and radioactive effluents from the facility. Although a theoretical calculation is often used to demonstrate compliance with regulations regarding airborne or external radiation, it cannot always be used in lieu of a physical survey.

Except for those cases where sources of radiation and radioactive material are well known and accurately and precisely controlled, it will usually be necessary that a physical survey be made with appropriate detection and measurement instruments to determine the nature and extent of radiation and radioactive material, or as a minimum, confirm the results of a theoretical determination.

A radiation protection program should include the following surveys for radioactive contamination and radiation:

1) In laboratory or plant areas (e.g., checking for contamination on bench tops, handling and storing equipment, clothing, hands)

2) While work is being done with radiation or radioactive materials (e.g., breathing zone air surveys; general air surveys, personnel exposure measurements, including eyes and extremities.)

3) In areas associated with disposal or release of radioactive materials (e.g., checking disposal containers and disposal sites; liquid, gas and solid effluents, filters and filter-duct systems)

The frequency of surveys will depend on the nature of the radioactive materials and their use. However, surveys should be performed prior to the use of radioactive materials in order to establish a baseline. The surveys should be repeated when radioactive materials are present, when the quantity or type of material present changes, or when changes occur in their

containment systems or methods of use. Repetitive surveys may also be necessary to control the location of radioactive materials in the handling system and in the case of the use of sealed sources outside a shielded container.

For operations involving materials in gas, liquid, or finely divided forms, the survey program should be designed to monitor the adequacy of containment and control of the materials involved. The
program should include air sampling, monitoring of effluents, and surveys to evaluate contamination of personnel, facilities and equipment.

The description of an air sampling program should include the area where samples will be taken, the frequency of sampling, and the location of the sampler with respect to workers' breathing zones. Assays performed to evaluate air samples and the methods used to relate results to actual personnel exposures should also be described.

The effluent monitoring program for releases to unrestricted areas should encompass all airborne and liquid radioactive material releases. Theoretical evaluations should be supplemented by stack monitoring, water sampling, and other environmental monitoring appropriate for the planned and potential releases.

The types, methods, and frequency of surveys should be described in the application.

ITEM 7 - Leak-Test Procedures. Sealed sources containing more than 100 microcuries of a beta or gamma emitter or more than 10 microcuries of an alpha emitter must be leak tested at 6-month intervals. Leak testing of alpha-particle-emitting sources containing more than 10 microcuries of an alpha emitter is required at 3-month intervals. If a commercial firm is to perform the leak tests, the name, address, and license number of the firm should be submitted. If the tests are to be performed using a commercial "kit", the name of the kit manufacturer or distributor and the kit model designation should be given. If the applicant intends to perform his own leak tests without the use of a commercial kit, the following information should be submitted:

1) Qualifications of personnel who will perform the leak tests;

2) Procedures and materials to be used in taking leak test samples;

3) The type, manufacturer's name, model number, and radiation detection and measurement characteristics of the instrument to be used for assay of test samples;

4) Instrument calibration procedures, including calibration source characteristics, make, and model number, and;

5) The method, including a sample calculation, to be used to convert instrument readings to units of activity, e.g., microcuries.

ITEM 8 - Waste Disposal

The procedures for disposing of byproduct material waste should be described. Under the Louisiana Radiation Regulations, a licensee may dispose of waste in the following ways:

1. by transfer to an authorized recipient as provided in LAC 33:XV.465 or in LAC 33:XV., Chapters 3, 13, or 14, or to the U. S. Department of Energy;

2. by decay in storage;

3. by release in effluents within the limits in LAC 33:XV.421; or

4. as authorized pursuant to LAC 33:XV.461, 462, 463, or 464.

ITEM 9a - Health Physics Program:

1. Records Management Program. Provisions for keeping and reviewing records of surveys; material inventories; personnel exposures; receipt, use, and disposal of materials, etc. should be described.

2. Instructions to Personnel. If a number of individuals will use radioactive material under the supervision of one or more of those persons named in the application, written instructions should be prepared and submitted with the license application in the form in which they will be distributed to those working with radioactive materials. These instructions should cover, but not necessarily be limited to:

   a) The availability, selection, and use of laboratory apparel and safety-related equipment and devices (e.g., laboratory coats, gloves, and remote pipetting devices).

b) Limitations and conditions to be met in handling liquid or contained (unencapsulated, dispersible, or volatile) radioactive materials and special laboratory equipment to be used in working with these types of materials. For example, the instructions should explain when operations with materials should be confined to a radiochemical fume hood or glove box and should specify the use of appropriate shielding and remote handling equipment when energetic beta- or gamma-emitting materials are to be used.

c) The performance of radiation survey and monitoring procedures for each area in which radioactive materials are to be used.

d) Safety precautions to be observed in the movement of radioactive materials between buildings, rooms, and areas within rooms.

e) Safety requirements for storage of radioactive materials, including labeling of containers of radioactive materials and posting and securing areas where radioactive materials are to be stored. This should include the storage of contaminated laboratory equipment such as glassware.

f) Requirements for posting of areas in which radioactive materials are used.

g) The availability and use of personnel monitoring devices, including the recording of radiation exposures and the procedures to be followed for the processing of personnel monitoring devices such as Thermoluminescent dosimeters and film badges in order to obtain personnel monitoring results.

h) Waste disposal procedures to be followed, including limitations on the disposal of liquid or other dispersible waste to the sanitary sewer and procedures for the collection, storage, and disposal of other wastes.

i) The maintenance of appropriate records.

j) The requirements for and the method of performing or having appropriate sealed source leak tests performed.

k) Good radiation safety practices, including the control of contamination, specification of acceptable removable and fixed contamination levels for both restricted and unrestricted areas, prohibition of smoking and the consumption of food or beverages in areas where radioactive materials may be used, and prohibition of the frequent transfer of potentially contaminated equipment between potentially contaminated areas and unrestricted areas.

l) Emergency procedures. These instructions should be addressed to all persons in all laboratory or facility areas where radioactive materials will be used, and should cover actions to be taken in case of such accidents involving radioactive material spills, fires, release or loss of material, or accidental contamination of personnel. Specifically, these instructions should (a) specify immediate actions to be taken in order to prevent or limit the contamination of personnel and areas, e.g., the shutting down of ventilation equipment, evacuation of contaminated and potentially contaminated areas, containment of any spills of radioactive material, (b) give the telephone numbers of individuals to be notified in case of emergency, and (c) instruct personnel in proper entry, decontamination and recovery operations for contaminated facilities.

m) Requirements and procedures for picking up, receiving and opening packages.

ITEM 9b - Physical Facilities

The facilities and equipment for each site of use should be described in detail. The proposed facilities and equipment for each operation to be conducted should be adequate to protect health and minimize danger to life and property. In describing available facilities and equipment, the following should be included as appropriate:

a. A drawing or sketch should be submitted showing the location of all such equipment and the relationship of areas where radioactive materials will be handled to unrestricted areas where radioactive materials will not be handled. In those programs where radioactive material may become airborne or
may be included in airborne effluents, the drawing or sketch should include a schematic description of the ventilation system annotated to show airflow rates, differential pressures, filtration and other effluent treatment equipment and air and effluent monitoring instruments.

b. Containers, devices, protective clothing, auxiliary shielding, general laboratory equipment, air sampling equipment, etc., actually employed in the daily use of material. Storage containers and facilities should provide both shielding and security for materials.

ITEM 10 and 11 - Health Physics and General Instrumentation:

Specify for each radiation detection instrument, the manufacturer's name and model number, the number of each type of instrument available, the type of radiation detected (alpha, beta, gamma, or neutron), the sensitivity range (milliroentgens per hour or counts per minute), the window thickness in $mg/cm^{2,}$ and the type of use. The type of use would normally be monitoring, surveying, assaying, or measuring.

Describe the instrument calibration procedure. State the frequency, and describe the methods and procedures for the calibration of survey and monitoring instruments, as well as any other instruments and systems used in the radiation protection program, such as measuring instruments used to assay sealed-source leak-test samples, contamination samples (e.g., air samples, surface "wipe" samples), and bioassay samples.

An adequate calibration of survey instruments usually cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Daily or other frequent checks of survey instruments should be supplemented every 6 months with a two-point calibration on each scale of each instrument with the two points separated by at least 50% of the scale. Survey instruments should also be calibrated following repair. A survey instrument may be considered properly calibrated when the instrument readings are within ±10 percent of the calculated or known values for each point checked. Readings within ±percent are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

If the applicant proposes to calibrate his survey instruments a detailed description of planned calibration procedures should be submitted. The description of calibration procedures should include as a minimum:

a. The manufacturer and model number of each radiation source to be used.

b. The nuclide and quantity of radioactive material contained in each source.

c. The accuracy of the source(s). The traceability of the source to a primary standard should be provided.

d. The step-by-step procedures, including associated radiation safety procedures; and

e. The name and pertinent experience of each person who will perform the calibrations.

If the applicant intends to contract out the calibration of instruments, the name, address, and license number of the firm should be specified together with the frequency of calibration. The applicant should contact the firm that will perform the calibrations to determine if information concerning calibrations procedures has been filed with the Department. If information concerning calibration procedures has not been filed, it should be obtained and submitted.

Quantitative measuring instruments used to monitor the adequacy of containment and contamination control such as those used for measuring leak test, air, effluent, bioassay, work area, and equipment contamination samples should usually be calibrated prior to each use. The procedures and frequency for calibration of such instruments should be submitted and should include:

a. The name of the manufacturer and model number of each of the standards to be used.

b. The nuclide and quantity of radioactive material contained in each of the standard sources.

c. A statement of the accuracy of each of the standard sources. The source accuracy should be as a minimum, ±5 percent of the stated value and traceable to a primary standard, such as that maintained by the National Bureau of Standards.

d. Step-by-step calibration procedures and, if appropriate, associated radiation safety procedures, and

e. The name and pertinent experience of each person who will perform the instrument calibrations.

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

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, 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 that 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?

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