



Texas Department of State Health Services Radiation Safety Licensing Branch

REGULATORY GUIDE 3.04

GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR BROAD USE OF RADIOACTIVE MATERIALS AT ACADEMIC INSTITUTIONS

I. Introduction

This describes the information the Department of State Health Services (DSHS or Agency) staff needs to evaluate license applications submitted by an institution for a license to use unspecified quantities and multiple types of radioactive material for research and educational purposes. This type of license is known as a "broad" license and is intended to accommodate those institutions involved in research programs where the demand is great for a variety of radioactive materials for many different uses.

In order for an institution to have a broad license, the institution must have a full-time Radiation Safety Officer (RSO) and/or staff, establish a sub-licensing program, and conduct an internal inspection program to audit the users of radioactive material. This type of license allows the institution to name the users of radioactive material within the institution and allows the institution to use any radioactive material as approved by the institution's Radiation Safety Committee (RSC) and within the requirements of Title 25 Texas Administrative Code (TAC) Chapter 289.

II. Instructions For Completing The Application

BRC Form 252-2 is used for license applications for a broad license. All items of this application should be completed in full so that a realistic review may be made of the institution's ability to conduct all phases of an extensive radioactive material program. Since the space provided on the application is limited, the applicant should append additional sheets as necessary. The application should be submitted in duplicate.

Specific items of the application are listed below with explanatory comments.

Item 1 - Self-explanatory.

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 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

Item 2 - Provide the building name and number for the radiation safety office and for all off-campus locations where radioactive material will be used. (This may be put on a supplemental sheet.)

Item 3 and 4 - Self-explanatory.

Item 5 - Put "Individuals approved by the Radiation Safety Committee (RSC)."

Item 6 - The RSO is the person who is designated as responsible for the radiation safety program, who maintains the license and associated records, and who is the primary contact with the Agency in administering the license. The RSO must have the authority to enforce radiation safety policy, suspend activities deemed unsafe, and require remedial action when necessary.

Item 7 - Under 7a, place as one item, "Any radioactive material with atomic number less than 84," for the bulk of material needed for research purposes. List any radionuclides needed in large quantities and alpha-emitting nuclides. Under 7c, list the maximum activity of any single radionuclide and the total activity of all radionuclides with atomic numbers less than 84. (See Appendix A for sample form.)

Item 8 - The applicant should describe the basic criteria that will be used by the RSC to evaluate each laboratory in which radioactive material will be used.

Item 9 - (See Sections V. and VI. for the required procedures.)

Item 10 - If a commercial service is to be used to calibrate survey instruments, that should be stated. If the institution plans to calibrate its own instruments, procedures for doing so must be submitted. (Regulatory Guide 5.2, "Guide for the Preparation of Survey Instrument Calibration Applications," may be obtained from the Agency.) Instruments should be calibrated at intervals not exceeding one year.

Item 11 - If a commercial service is to be used to perform leak tests, that should be stated. If the institution plans to test its own sources for leakage, procedures for doing so must be submitted. (Regulatory Guide 5.1, "Guide for the Preparation of Leak Test Applications," may be obtained from the Agency.) These tests must be made at intervals not exceeding six months, and records of each test must be maintained. Note that sources designed to emit alpha particles must be leak tested at intervals not to exceed three months.

Item 12 - In addition to the resumes of the RSO and RSC members, a description should be included of the minimum radiation safety training to be given to students who will use radioactive material.

Item 13 - Waste disposal procedure should be covered in the Radiation Protection Procedures. (See Section VI.)

Item 14 – See 25 TAC §289.252(gg) to determine if financial assurance must be provided. Unless license authorizations include large amounts of long-lived radioactive material (i.e., half-lives of greater than 120 days), financial assurance is not required and financial qualification can be established via self-attestation on BRC Form 252-1, Business Information Form.

Item 15 - The application must be signed by a person duly authorized to commit the institution to the performance of the activities as specified in the application. This will be the University President unless an alternative representative is designated by the President. Renewals of existing licenses can be signed by the currently approved RSO.

III. Radiation Safety Officer (RSO)

An RSO must be appointed to be responsible for the daily operation of the institution's radiation safety program. A description of the RSO's training and experience with radioactive material and in the field of radiation safety must be provided.

IV. Radiation Safety Committee (RSC)

An RSC must be established in conformance with 25 TAC §289.252(h). This committee should be composed of at least five members to evaluate all proposals for use of radioactive material within that institution. Membership of the committee should draw from faculty members of departments that use radioactive material and a person experienced in radiation safety and/or health physics. In addition, this committee should have one or more persons representing the institution's administration in its membership. Names and qualifications of the committee members must be submitted. Confirm that a quorum of at least a simple majority of the committee, including the chairman, the RSO, and the representative from management must be present for the committee to conduct official business.

V. Administrative Procedures

The applicant must submit two copies of the Administrative Procedures outlining how the RSC will manage the use of radioactive material within the institution. The Administrative Procedures should delineate the following:

- A. Outline the specific responsibilities and authority of the RSC, including but not limited to, establishing policy for safe use of radioactive material, approving use of radioactive material, monitoring use of radioactive material by sub-licensees, and suspending operations deemed unsafe.
- B. Frequency at which the full committee meets to discuss and take appropriate actions relating to the use of radioactive material.

- C. Method employed for maintaining records of the committee's proceedings.
- D. The means by which the committee will determine whether an individual is qualified to use radioactive material experimentally within the institution.
- E. The responsibilities and authority of the RSO.
- F. Appropriate forms and instructions for making application to the committee for radioactive material use, and for the committee to authorize such use. The forms should include all appropriate items of the Agency application and license forms.
- G. Procedures for procuring radioactive material, maintaining inventories, controlling possession limits, and coordinating and controlling waste disposal.
- H. Procedures and criteria for periodic inspection of sub-licensees by the RSO or the radiation safety staff to see that sub-license conditions and institutional safety procedures are being followed.

VI. Radiation Safety Procedures

A formal set of rules and procedures for procurement and safe handling of radioactive material within the institution must be established by the RSC. A copy of these rules and procedures should be made available to all personnel under the jurisdiction of the RSC. Two copies must accompany the license application. The written radiation protection procedures should have a table of contents, have serially numbered pages, and include:

- A. Procedures for ordering radioactive material, receipt of radioactive material during on and off-duty hours, and notification of responsible persons upon receipt of radioactive material. These procedures should be adequate to ensure that possession limits are not exceeded, that radioactive material is secured against unauthorized removal at all times, and that radiation levels in unrestricted areas do not exceed the limits specified in 25 TAC §289.202(n).
- B. Procedures for examining incoming packages for leakage, contamination or damage, and for safely opening packages. The monitoring should be performed as soon as practicable after receipt of the package of radioactive material, but no later than three hours after the package is received at the institution during normal working hours. The procedures may vary depending upon the quantity of radioactive material received, but should, at a minimum, include instructions for surveying packages, wearing gloves while opening packages, and checking packing material for contamination after opening [see 25 TAC §289.202(ee)].
- C. Procedures for recording receipt, use, transfer, and disposal of radioactive material.

- D. Guidelines for restricting access to areas where radioactive material is used or stored and for posting warning signs.
- E. Criteria for handling liquid or loose radioactive materials and the laboratory equipment to be used in working with them. For example, explain what materials and what operations should be confined to radiochemical fume hoods or glove boxes. Designate the shielding or remote handling equipment to be used when radioactive material is handled in millicurie or greater amounts.
- F. Procedures for storing and maintaining accountability of sealed sources. (Provide sample form and instructions.)
- G. Procedures for monitoring personnel exposure (film badges, TLD, etc.).
- H. Standard operating procedures (laboratory rules) to help prevent contamination from occurring (see Appendix C).
- I. Procedures for managing spills, contamination and radiation accidents.
- J. Procedures individual users will follow when performing and recording radiation and contamination surveys (see Appendix B). The individual users should supplement the surveys performed by the radiation safety staff, and the survey equipment that they must have should be specified. The procedures should include analysis procedures (i.e., equipment methods, calculations, comparison standards and minimum detectable activities) for various radioactive materials potentially involved.
- K. Instructions provided to animal caretakers for handling of animals treated (injected) with radioactive materials, for handling animal waste and carcasses, for cleaning and decontamination of animal cages, and for ensuring animal rooms are locked or otherwise secured unless attended by authorized users of radioactive material.
- L. A complete description of the specific methods for waste management and disposal of radioactive material. A licensee may dispose of waste by:
 - 1. Transfer to a person properly licensed to receive such waste.
 - 2. Release into a sanitary sewer in conformance with 25 TAC §289.202(gg).
 - 3. Storage until activity has decayed to a specified level and release to sewer or dump after labels have been removed.
 - 4. Disposal of low concentrations of carbon-14, hydrogen-3, or iodine-125 in accordance with the provisions of 25 TAC §289.202(fff).

NOTE: No licensee may dispose of radioactive material by incineration, burial, or

release to the atmosphere unless specifically authorized by the Agency.

M. Emergency procedures that will be posted in laboratory areas where radioactive material is used. These instructions should:

1. Describe immediate actions to be taken for prevention of contamination of personnel and work areas, such as turning off the ventilation, evacuating the areas, containing the spill, etc.; and
2. State the telephone numbers of the responsible persons to notify in case of an emergency.

Appendix A

SAMPLE FORM
(page 1/2)

A. Any radioactive material with Atomic Number less than 84	A. Any (except sealed sources, gases or aerosols)	A. 500 mCi of any single radionuclide; Total not to exceed 200 Ci	A. Research and education.
B. Any radioactive material with Atomic Number less than 84	B. Sealed sources and devices	B. Any single source not to exceed 500 mCi; Total not to exceed 200 Ci	B. Research and education.
C. Any radioactive material (as per letter dated Month Day, Year)	C. Sealed sources and devices	C. Any single source not to exceed 5 Ci Total not to exceed 200 Ci	C. Research and education.
D. Any radioactive material with Atomic Number of 84 or greater, except special nuclear material	D. Any (except sealed sources)	D. 500 mCi of any single radionuclide Total not to exceed 200 Ci	D. Research and education.
E. Any radioactive material with Atomic	E. Sealed sources and devices	E. Any single source not to exceed 10 mCi Total not to exceed	E. Research and education.

Number of 84 or greater, except special nuclear material

50 mCi

Appendix A (continued)

SAMPLE FORM
(page 2/2)

F. Tc-99m/ Mo-99	F. Tc-99m generators	F. 10 Ci	F. Medical research, diagnosis, and education.
G. I-131	G. Any except aerosols	G. 1 Ci	G. Medical research, diagnosis, therapy and education.
H. Xe-133	H. Any	H. 250 mCi	H. Medical research, diagnosis, and education.
I. Ir-192	I. Sealed Sources (Manufacturer and Model Number)	I. Two sources not to exceed 12 Ci; Total 23 Ci	I. One source (set) for treatment of humans with a <u>Manufacturer</u> HDR remote control brachytherapy unit and the other source (set) for storage in its authorized shipping container during periods of source exchange.
E. Any radio- active material with Atomic Number of 84 or greater, except special nuclear material	E. Sealed sources and devices	E. Any single source not to exceed 10 mCi Total not to exceed 50 mCi	E. Medical research, diagnosis, therapy and education.

Appendix B

METHODS AND FREQUENCY FOR CONDUCTING RADIATION SURVEYS

I. Introduction

When radioactive material is handled in the form of solutions or powders in a laboratory, both radiation surveys and contamination surveys should be performed to prevent unnecessary radiation exposure to personnel and to prevent the spread of contamination throughout the facility. Radiation surveys are performed using a radiation survey instrument, and contamination surveys are performed by taking wipe samples from surfaces likely to be contaminated in the facility.

II. Methods Of Surveys

Suggested methods for performing the two types of surveys are given below. Records of these surveys should be maintained for inspection by the Agency and for reference to determine whether the radiation levels or the contamination levels remain constant or increase over a period of time.

- A. Radiation Level Surveys - A survey instrument capable of measuring levels as low as 0.1 mR/hr should be used and the results recorded on a standard form showing location, date, person performing survey, instrument used, exposure levels, and corrective action taken, if any. A sketch of the area should be used to make an easily prepared and easily understood survey record.
- B. Contamination Level Surveys - A series of wipes using filter papers or swatches of cloth should be taken from those surfaces where contamination could exist. (Areas where solutions are prepared, incoming packages are received, pipetting is performed, etc., are areas that may be contaminated.) The wipes should be numbered or labeled and their location indicated on the sketch record as previously described. Each wipe should be rubbed over a surface area of about 100 square centimeters to maintain a consistent means of determining the amount of removable contamination. The wipes may be counted using a scintillation well counter, a proportional counter, or any other detector capable of detecting the small amount of contamination on the sample.

III. Frequency Of Surveys

The frequency of surveys depends on the amount and type of radioactive material used. The greater the workload, the more often surveys should be performed.

Examples that may be useful in deciding the frequency of surveys are provided here

- A. Low Level Areas - At least once a month. Areas where in vitro tests are performed, samples are analyzed, etc. (samples usually less than 100 microcuries)

Appendix B (Continued)

METHODS AND FREQUENCY FOR CONDUCTING RADIATION SURVEYS

- B. Medium Level Areas - Not less than once a week - Areas where millicurie amounts of material are handled.

- C. High Level Areas - Not less than once a day - Areas used for storage of active solutions, preparation of materials, fume hoods, etc. (usually curie amounts).

IV. Acceptable Limits

- A. Radiation Levels - In no unrestricted (uncontrolled) area should radiation levels exist such that a person could receive 100 mrem in any one year or 2 mrem in any one hour. If such areas are found, measures should be taken to eliminate the excessive radiation levels. Additional shielding or relocation of radioactive material may be required. For restricted areas, the applicant should establish acceptable radiation levels that are as low as reasonably achievable.

- B. Contamination Limits - If the wipe samples counted indicate removable contamination levels greater than those in 25TAC §289.202(ggg)(6), the area should be cleaned until the contamination has been removed. This action should help prevent the spread of contamination and ingestion of activity by personnel.

Appendix C

GENERAL LABORATORY RULES

Following here are rules that could be used for a laboratory using or preparing radioactive material. The applicant should develop rules specific to their individual needs and reflect the actual laboratory situation. Use of material that may become airborne (aerosols, gases, or volatiles) will require additional rules, as will alpha emitters and the use of large, sealed sources. Rules should be written as directions to be followed by employees.

1. Wear laboratory coats or other protective clothing at all times.
2. Wear disposable gloves at all times while handling radioactive material.
3. Monitor hands/clothing for contamination after each use & before leaving the area.
4. Use remote handling devices and shielded containers with millicurie amounts of activity.
5. Do not eat, drink, smoke, or apply cosmetics where radioactive material is stored/used.
6. Do not store food, drink, or personal effects with radioactive material.
7. Wear personnel monitoring devices (film badge or TLD) at all times. These devices should be worn at chest or waist level. Personnel monitoring devices, should be stored in a designated low background area, as should the control badge.
8. Wear TLD finger badges when handling millicurie amounts of radioactivity.
9. Dispose of radioactive waste in specially-labeled and properly- shielded receptacles.
10. Never pipette by mouth.
11. Survey areas where radioactive material is used in uncontained form after each procedure or at the end of the day. Decontaminate if necessary.
12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.
13. Transport radioactive material in shielded containers when necessary to protect against

external radiation exposure.

14. Work over surfaces that are easily cleaned or covered with disposable, absorbent coverings when handling open solutions of radioactive material. Work only in designated restricted use areas. Process volatile radioactive materials in fume hoods. Use glove boxes when processing alpha-emitting materials that must be contained to prevent contamination of personnel or the environment.