



Texas Department of State Health Services Radiation Safety Licensing Branch

Regulatory Guide 5.1

Revision Date: October 2014

Guide for the Preparation of Applications for Leak-Testing Services

I. INTRODUCTION

A. Licensing Process

The acquisition, possession, use, manufacture, production, transport, transfer, and processing of radioactive material in Texas shall be authorized by the Texas Department of State Health Services (DSHS), Radiation Safety Licensing Branch. The branch issues such authorization as a license. A license indicates what type, quantity, form, and use of radioactive material is authorized and any special conditions under which the radioactive material shall be used. This guide describes the process for application for a license and for amendment, renewal, and termination of a license.

B. DSHS Contacts

The DSHS radiation control program maintains an Internet site. The site contains the rules and forms referenced in this regulatory guide, as well as information on who to contact at DSHS with questions, information on the activities and structure of the department, topics of interest about radiation, and links to other radiation-related web sites.

The DSHS Internet site is located at: <http://www.dshs.state.tx.us/radiation>

If you do not have access to the world-wide web and need additional information, please call (512) 834-6688 and ask for the following:

Industrial Licensing Program - for questions regarding the regulation of radioactive materials for the purpose of analyzing samples for radioactivity and the application for specific licenses and any related correspondence.

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 (department), 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 department 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: Manger, 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 department at (512) 834-6688 or accessing our web page at www.dshs.state.tx.us/radiation

II. APPLICABLE REGULATIONS

A. The requirements of the following sections of Title 25, Texas Administrative Code (TAC), Chapter 289, apply to the use of radioactive material in Leak-Testing Services:

§289.201 “General Provisions for Radioactive Material”

§289.202 “Standards for Protection Against Radiation from Radioactive Material”

§289.203 “Notices, Instructions, and Reports to Workers; Inspections”

§289.204 “Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services”

§289.205 “Hearing and Enforcement Procedures”

§289.251 “Exemptions, General Licenses, and General License Acknowledgements”

§289.252 “Licensing of Radioactive Material”

§289.257 “Packaging and Transportation of Radioactive Material”

B. It is the licensee's responsibility to ensure that its facility and any additional authorized sites are provided with copies of the applicable rules. These rules may be downloaded from the DSHS Internet site <http://www.dshs.state.tx.us/radiation>. If you do not have access to the world-wide web you may request one copy of the applicable rules. For a charge, you may request rules on disk or more than one hard copy of the rules.

III. FILING AN APPLICATION

A. GENERAL

25 TAC, Chapter 289, this guide, forms, and other guidance documents are available on the DSHS Internet site: <http://www.dshs.state.tx.us/radiation>. Each applicant must submit the following forms in duplicate:

- **RC Form 252-1 (Business Information Form)**

Applicants must sign and submit, in duplicate, a completed Business Information Form. The applicant is not required to provide financial assurance. Select top check box on the business information form.

- **RC Form 252-2 (Application for Radioactive Materials License)**

Space provided on the application form is limited, so 8.5” x 11” paper should be used to append additional pages. Each page submitted with the application should be identified and keyed to the item number on RC Form 252-2 to which it applies. Two copies of the application and all attachments must be submitted, with another copy retained by the applicant. All application items must be addressed in sufficient detail to demonstrate that equipment, facilities, personnel qualifications and procedures are adequate to protect public health and safety or property.

III. FILING AN APPLICATION (Continued)

B. LICENSE FEES

- **New Application**

A fee must be submitted with each new application. Refer to 25 TAC §289.204 to determine the fee that should accompany the application. Each additional storage site will add 25% to the base license application fee. You may contact the accounting office at (512) 834-6688 to verify the total application fee required. Review of the application will not begin until the proper fee is received by the DSHS. The check or money order should be made payable to the Department of State Health Services.

Mail the completed new license application and the required license fee to:

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

- **Biannual Fee**

Once a license has been issued, a nonrefundable fee must be paid biannually for each radioactive material license. The fee must be paid in full for 2 years on or before the last day of the expiration month of the license. For example, if the license expires September 30, 2023, the biannual fees are due on or before September 30 of each odd-numbered calendar year. You will receive a bill from the DSHS for your biannual fee approximately 60 days prior to the fee due date.

- **License Renewal or Amendment**

Do not submit a fee with the request for renewal or amendment. If an amendment changes or adds a category of license or adds an additional authorized use site, the biannual fee will be adjusted accordingly. The adjustments will be reflected on your next fee bill.

The department maintains a separate address for regular correspondence. Submit your license renewal or amendment request to the following address:

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

III. FILING AN APPLICATION (Continued)

C. COMPLETING THE APPLICATION

1. Submit RC Form 252-2, "Application for Radioactive Material License".
2. Complete all items on the application in sufficient detail to allow the license reviewers to make a complete evaluation of the applicant's facilities, equipment, personnel training and qualifications and radiation safety program are adequate to protect health and minimize danger to life and property.
3. Submit two copies of the application and all attachments and keep a complete copy for your records.
4. Complete Items 1-15 on the application.
5. Additional sheets will be necessary to submit all of the information in items 8-15 of the application. Identify each separate sheet or document submitted with the application by referencing the application item number to which it refers.
6. Submit all documentation, including pages, sketches, and drawings, on 8-1/2 x 11 inch paper to ease handling and review. If larger drawings are necessary, they should be folded to 8-1/2 x 11 inches.

IV. CONTENTS OF AN APPLICATION

This section provides instructions on completing each item listed in RC Form 252-2, "Application for a Radioactive Materials License."

Item 1 – LEGAL BUSINESS NAME AND MAILING ADDRESS OF APPLICANT

List the name, a state of Texas mailing address, and telephone number of the individual or company to whom the license will be issued. If available, please include an e-mail address and fax number. Also complete and submit RC Form 252-1, "Business Information Form," available from the department's website.

An applicant's corporation must be registered with the Texas Secretary of State's Corporations Section. If an assumed name is to be included, it will be identified as the name the applicant is doing business as (d/b/a) and must also be registered. For example, "ABC Corporation d/b/a ABC Enterprises of Texas." Business registration should be verified by contacting the Texas Secretary of State's Corporations Section at (512) 475-2755 or on the Internet at <http://www.sos.state.tx.us/corp/sosda/index.shtml>.

If the applicant is an individual, the individual should be acting in a private capacity, and the use of the radioactive material should not be connected with the individual's employment with a corporation or other legal entity.

Item 2 - LOCATIONS WHERE RADIOACTIVE MATERIAL WILL BE USED

Specify all use and/or storage locations by designating the street address, city, and state. A post office box address is not acceptable in Item 2. Note: The number of authorized sites will affect the amount of the license fee. Each additional storage and/or records location will add 25% to the base license fee.

IV. CONTENTS OF AN APPLICATION (Continued)

Item 3 – THIS APPLICATION IS FOR

Identify if the application is for a new license or renewal of an existing license. If the application is for renewal of a license, provide the existing license number. If a previous license was or is currently held from Texas or another jurisdiction, include that information.

Item 4 - LOCATION WHERE RECORDS WILL BE KEPT

This is the location that will be listed on the license as the main site and the site to which all correspondence is mailed unless a post office box service is maintained. The main site is the site where the Radiation Safety Officer is routinely available and can receive correspondence without delay; and where copies of records for the entire license are maintained for inspection by the department.

Item 5 - INDIVIDUAL USERS AND THEIR TITLES

List the names and titles of the individuals who will be taking leak tests, or analyzing leak tests. Submit a resume of training and experience to include formal academic training and on the job training in performing leak-test on the specified equipment. It should also describe each individual's experience in counting and interpreting leak-tests sample results.

Item 6 - RADIATION SAFETY OFFICER (RSO)

The RSO is the person designated to be responsible for the day-to-day radiation safety program. The RSO maintains all records required by department rules, and is the primary contact with the department on matters pertaining to the license and the use of radioactive materials. The RSO must have the authority to enforce radiation safety policy, suspend activities deemed unsafe, and require remedial action when necessary. Submit the following information concerning the RSO:

- The RSO's educational background and specific training and experience with radioactive materials in the field of radiation safety.
- Indicate the name of the RSO and telephone number(s), FAX number(s), and electronic mail address(es) where the RSO may be contacted.

Item 7 – RADIOACTIVE MATERIALS DATA

- 7a. List the radionuclides expected to be found on samples and in any standards of sealed sources needed for calibration (except for exempt sources).
- 7b. List the chemical and physical form.
- 7c. List the maximum quantity (in millicuries) of each radionuclide to be possessed at any one time. The possession limit for each radionuclide should include material held as radioactive waste.
- 7d. Describe the intended use for each radionuclide and form listed in items 7a and 7b.

Licensees are encouraged to perform frequent inventory checks to guard against loss or theft.

IV. CONTENTS OF AN APPLICATION (Continued)

Item 8 – FACILITIES

1. Describe the permanent storage facility for radioactive material, to include the following:
 - a. Method of restricting access to radioactive material to authorized users and other trained workers, including the method of controlling access to restricted areas, radiation areas, and high radiation areas. Indicate security precautions to be taken to prevent theft or unauthorized use of the radioactive materials.
 - b. Provide a diagram and description of the facility where radioactive materials will be stored and/or used. Describe the facilities to be used for receiving, storing and counting wipes. Indicate its relation to and distance from occupied areas within the facility and adjacent areas that may be occupied. Describe and label all adjacent areas to your facility (parking lot, neighboring buildings, streets, etc.). If your facility is a multistory and/or multitenant building, identify all floors and their uses, including areas occupied by other tenants.
 - c. Describe the kinds of sealed sources or sources in devices to be leak-tested [25 TAC §289.201(g)]. For sources in devices, specify the kinds of devices to be leak-tested, for example, gas chromatographs, portable moisture-density gauges, explosive detectors, fixed gauges (such as density gauges, level gauges, or gauges for measuring weight, bulk, moisture, thickness), and others appropriate to your proposed leak-testing program.
 - d. Indicate construction materials used and the dimensions of the storage location, including wall thicknesses.
 - e. Describe the dose assessment measurements made to ensure that doses to radiation workers and individual members of the public will be compliant with the individual members of the public dose limits and as low as reasonably achievable (ALARA). New applicants may maintain the results of dose assessment measurements on file for inspection by the department. Applicants for license renewal should submit the results of dose assessment measurements with their application.
2. Identify the owner of the proposed storage facility. If the facility is owned by another company, provide a letter from the owner or the owner's agent, acknowledging that they are aware that you are storing and/or using devices containing radioactive material on the property. Radioactive material shall not be used or stored in residential locations unless specifically authorized by the agency [25 TAC §289.252(x)(3)].

Item 9 - OPERATING, SAFETY, AND EMERGENCY PROCEDURES

The purpose of operating, safety, and emergency procedures is to provide personnel with clear and specific guidance and instructions for the use of radioactive material. The manual should include, but not be limited to the following topics:

1. Management Structure and Its Responsibilities Provide a description of the management structure, and the RSO's position in that structure. The RSO should assume control and have authority to institute corrective actions, including shutdown of operations when necessary in emergency situations or unsafe conditions. RSO duties are described in 25 TAC §289.252(f)(3).

IV. CONTENTS OF AN APPLICATION (Continued)

2. Radiation Safety Officer Duties Explain the RSO's duties in the company with emphasis on overseeing the radiation safety program. You may refer to 25 TAC §289.252(f)(3) for a listing of the minimum duties to be completed by the RSO.
3. Individual Monitoring Devices (if necessary) Individual personnel monitoring devices must be supplied to and worn by occupational workers likely to exceed 500 mrem (5 mSv) in one year. Refer to 25 TAC §289.202(q)(1) for additional monitoring requirements for minors, declared pregnant women, or occupational workers entering a high or very high radiation area. Individual monitoring devices shall meet the requirements of 25 TAC §289.202(p)(3). Describe the method of monitoring personnel exposure. Note that ring badges may be required for persons handling millicurie amounts of activity.
4. Emergency Procedures Describe methods for coping with spills and personnel contamination, radiation incidents, excessive individual exposures, lost or stolen sources, and significant facility contamination. Also, describe the actions to be taken by the RSO when emergency situations occur.

Provide instructions on what to do if sources or devices are found to be leaking or excessive radiation levels are found around the devices. These instructions should include procedures for proper notification to customer personnel, means of preventing and controlling the spread of contamination, and means of obtaining professional assistance, if needed. A source is to be considered leaking if it has 0.005 μCi (185 Bq) of removable contamination on its surface, or if it leaks 0.001 μCi (37 Bq) of daughter products in 24 hours. The customer shall be informed that the sealed sources is "leaking" or "not leaking".

NOTE: Please see the following referenced material for additional information.

- Radiation incidents and excessive individual exposures - 25 TAC §289.202(xx), "*Notification of Incidents,*" and 25 TAC §289.202(yy), "*Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.*"
 - Lost or stolen sources - 25 TAC §289.202(ww), "*Reports of Stolen, Lost, or Missing Licensed Sources of Radiation.*"
 - Significant facility contamination - 25 TAC §289.202(xx), "*Notification of Incidents.*"
5. Recordkeeping Provide a description of all records that will be maintained to document operations involving the use of radioactive material. Records should include, but not be limited to: Receipt, transfer, and disposal, leak tests, individual monitoring reports (if applicable); and training. Records should include identification of each source or device (manufacturer, model number, serial number, isotope, quantity; identification of each customer (name, address, contact person); radiation survey measurements, as appropriate; date of test and date of next scheduled test; information on test methods use (i.e., type of wipe such as dry filter paper or wet cloth swipe and areas wiped); leak-test results expressed in microcuries of alpha, beta or gamma radiation for each area wiped; and identification of the individual who performed the test. You should include a copy of the leak-test certificate you will supply to customers.

IV. CONTENTS OF AN APPLICATION (Continued)

6. Equipment Maintenance and Inspection Procedures Provide a description of the standard source(s) and the procedures to be used to calibrate the counting equipment. The activity of the standard source(s) should be of the same order of magnitude as the leak test criteria, i.e., sub-microcurie amounts. Standard source(s) must also be selected to present the same types of radiation to the counting equipment as the samples. For example, with a cesium-137 wipe having both beta and gamma emissions, if the beta emission is to be counted by the detection equipment, the standard source must be a beta source also. Similarly, sealed radium standard source(s) would be appropriate only for gamma counting or radium leak test samples.
7. Posting of Areas and Labeling of Containers Provide a description of storage area signs and specify where the items required by 25 TAC §289.203(b) will be posted. (relating to Notices, Instructions, and Reports to Workers; Inspections), "Instructions to Workers".
8. Handling Procedures Provide instructions for performing the wipe test, including material to use and methods of handling samples to prevent or minimize exposure to personnel. These should include specific methods for foil sources, plated sources, sealed sources of large activity, and sealed and/or plated radium or thorium sources if your service is to encompass such testing. Include the method used for counting the sample, standard source(s), and background, and the calculations necessary to derive, in microcuries, the amount of removable contamination present to the source, or in the case of radium, the amount leaking from the source in 24 hours. The particular extrapolation method to be used for radium or thorium needles and plaques, or any other source for which sample collection is indirect (collection of daughter products), should also be described.
9. Leak- Testing Kit If a commercial leak- test kit is to be distributed to customers, a sample kit with its instruction sheet must be provided for evaluation. If you will use your own "kit", you must specify and describe the components [25 TAC §289.201(g)(1)(H)].
10. Transportation Describe the procedures for transporting radioactive material and opening packages containing specifically licensed material. The transport container must comply with the applicable U.S. Department of Transportation regulations. This includes providing security seals, bracing packages during transport, and labeling requirements [25 TAC §289.257].

Item 10 - RADIATION DETECTION INSTRUMENTATION

Radiation survey meters shall be available for the applicant to perform surveys and demonstrate compliance with 25 TAC §289.202(p) and for accident response. The applicant must provide the manufacturer and model number of each type of survey instrument to be possessed.

Leak-Testing Services List the equipment available for radiation surveys and for analyzing wipes. A description of the counting equipment including the make, model number, and minimum detectable activity. For each isotope to be leak tested, the emissions to be measured and the method of detection should also be specified. For example, a radium source leak testing may measure the total alpha emission or gamma emission of radon plus daughters, depending upon the proposed sample collection method. Leak test results must be reported in microcuries. Negative results may be reported as "less than ___ microcuries" where the minimum detectable activity of the counting equipment is specified in the blank space.

IV. CONTENTS OF AN APPLICATION (Continued)

Calibration of Instruments Submit procedures if survey meter calibrations are performed at your facility. If your survey meters are sent out for calibration, submit a statement that calibrations will be performed by persons licensed to perform this service by the U.S. Nuclear Regulatory Commission or an Agreement State and that a copy of this license will be kept on file with the calibration certificates.

Item 11 - LEAK TESTING

Provide a detailed description of the procedures and analyses to be performed on any sealed sources you possess.

Item 12 - TRAINING AND EXPERIENCE

Submit a resume of training and experience to include formal academic training and on the job training in performing leak-test on the specified equipment. It should also describe each individual's experience in counting and interpreting leak-tests sample results. Guidelines on training and experience are:

- I. Formal training should encompass the following topics:
 - a) The principles and practices of radiation protections to include biological effects of radiation;
 - b) Radioactivity measurements, monitoring techniques, and the use of instruments;
 - c) Mathematics and calculations basic to the use and measurement of radioactivity.
- II. On-the-job training should encompass training in leak-testing the typical sources and devices specified, including performing independent analysis of leak-test samples. For individuals who have completed specific training presented by the manufacturers of the listed sources and devices, include copies of certificates or statements of training.

Item 13 - WASTE DISPOSAL

The applicant must describe how the radioactive material will be disposed of when it is no longer needed or can no longer be used. Disposal of radioactive material shall satisfy the general requirements in 25 TAC §289.252(cc). Waste disposal can usually be accomplished by returning all sources to the manufacturer. Disposal options also include the original supplier, a commercial firm licensed by the NRC or an agreement state to accept radioactive waste from other persons, or another specific licensee authorized to possess the radioactive material. All records of receipt, transfer, and disposal as well as all survey records pertaining to these actions shall be retained for DSHS inspection.

Item 14 - FINANCIAL QUALIFICATION AND FINANCIAL ASSURANCE

Complete all applicable areas on the Business Information Form (RC Form 252-1) and mark the first box at the top of page 1 to self-attest.

Item 15 – CERTIFICATION

The application must be dated and signed by a representative of the corporation or legal entity who is authorized to sign official documents and to certify that the application contains information that is true and correct to the best of the applicant's knowledge and belief. All unsigned applications will be returned for proper signature.

IV. CONTENTS OF AN APPLICATION (Continued)

Submit a completed RC Form 252-1 (Business Information Form) with the application. Mail the completed application, all attachments and the new license application fee to:

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

V. LICENSE RENEWAL

Absent any actions by the department or the licensee, a license remains in effect for ten years. An application for license renewal must be received by the department. This filing will ensure that the license does not expire until final action on the application has been taken. Because of advances in radiation safety techniques, changes in operations during the term of the license and DSHS rule changes, a complete renewal application must be submitted like the original application. For personnel added since the license was issued, a statement must confirm that the training and experience of new workers is in accordance with Item 12 of the application. If the application has made any changes in the training program, address those changes in Item 12 of the application. DSHS should be contacted directly for assistance in answering questions concerning the renewal and the procedure for addressing specific items.

Submit a completed RC Form 252-1 (Business Information Form) with the application.

Mail the completed application and all attachments to:

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

VI. LICENSE AMENDMENT OR TERMINATION

A. AMENDMENT

1. Submit an amendment request by letter, rather than on an application form. Always reference your license number when corresponding with DSHS. Amendments submitted on an application form may cause a processing delay.
2. Specify exactly what you want changed on the license. Always furnish a justification for the request.
3. Plan ahead whenever possible. For instance, if you have placed a bid on a job and know that an amendment to the license will be required (i.e., new storage/use location, additional radioactive material, etc.), forward your request for amendment to DSHS immediately. **PLEASE DO NOT WAIT** until after you are awarded the contract to request an amendment.
4. You will receive your license amendment by mail.
5. Always submit the request in duplicate, including attachments. For licensees with more than one permanent use/storage facility listed on the license or for amendment requests, you may be asked to submit more than two copies of your request. If you are asked to submit several additional copies of the request to the department, it would be advantageous to always submit that requested number of copies with future amendment requests.

VI. LICENSE AMENDMENT OR TERMINATION (Continued)

6. Send routine amendment requests separately from amendment requests that are more complex. For example, if you are changing RSO and also need to release a permanent storage/use facility for unrestricted use, you should submit each request in separate letters. Many times DSHS will perform a confirming close-out survey of your facilities before they are authorized to be released for unrestricted use. This will cause a delay in processing the requested RSO change.
7. If you have a license and a certificate of registration (an authorization for the use of X-Ray Machines) or multiples of either, always submit the changes that affect the radioactive material license to the Industrial Licensing Program and changes that affect the certificate of registration to the Industrial Registration Program. Submit changes that affect both documents to each program as separate requests.
8. When requesting the relocation of a permanent storage/use facility, note that the new facility must be authorized on the license before relocation can occur. After the amendment is issued and you have relocated to your new facility it is important that you submit a request to terminate the former facility. This request should be accompanied by a close-out radiation survey [25 TAC §289.202(ccc)] or last leak tests record.
9. The department will accept most facsimile transmissions as a formal request for amendment. The fax number is (512) 834-6690. Please limit facsimiles to no more than ten pages, thus originals may **NOT** need to be sent regular mail.

B. TERMINATION

1. To terminate your license, the department requires the following.
 - a. Request should specify that you want to **terminate** the license.
 - b. Copies of surveys (or current leak tests) required by 25 TAC §289.202(p), if applicable.
 - c. All fees shall be paid/current. Not paying your biannual fee does **NOT** automatically terminate your license.
 - d. Documentation of radioactive material disposition and radiation surveys (or current leak tests) required by 25 TAC §289.252(y).
 - e. All Notices of Violation shall be resolved through the DSHS Policy/Standards/Quality Assurance's Radiation Group.
2. DSHS reserves the right to conduct a confirming radiation survey and facility evaluation prior to the release of controlled areas for unrestricted use. It is the licensee's responsibility to decontaminate facilities to levels allowing release for unrestricted use. If residual radiation levels or contamination levels exceed the applicable release limits contained in §289.202, your license will not be terminated until release limits have been met.

Mail the license amendment or termination requests and any attachments to:

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

You may also fax the license amendment or termination request to:

(512) 834-6690