



Texas Department of State Health Services Radiation Safety Licensing Branch

Regulatory Guide 2.5

Issuance Date: October 2008

Guide for the Preparation of Radioactive Material License Applications for the Use of Portable X-Ray Fluorescence (XRF) Gauging Devices

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. There are two license types: general license and specific license. This guide describes the process for application for a specific license and for amendment, renewal, and termination of a license.

Important Note: Possession and use of radioactive material contained in Portable XRF Gauging Devices is typically available under a general license provision. Verify with your manufacturer/distributor if the device you require may qualify for distribution under a general license provision. For more information about general license provisions, please refer to Title 25 Texas Administrative Code (25 TAC) §289.251(f).

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 Portable XRF Gauging Devices and the application for a radioactive material license 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 the 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 Portable X-Ray Fluorescence (XRF) Gauging Device operations:

§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, including a certification statement of financial qualification to conduct the requested activity, including any decontamination, decommissioning, reclamation and disposal [25 TAC §289.251(jj)(8)].

- **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 application 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, 2009, 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," for the use of Portable XRF Gauging Devices.
2. Complete all items on the application in sufficient detail to allow the license reviewers to make a complete evaluation of the program for use of radioactive material in Portable XRF Gauging Devices.
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 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 storage or use locations by designating the street address, city, and state, or by designating a descriptive address. A post office box address is not acceptable in Item 2. The number of authorized sites will affect the amount of license fee. Each additional storage and/or records location will add 25% to the base license fee. Also, indicate whether Portable XRF Gauging Devices will be used at temporary jobsites throughout Texas.

IV. CONTENTS OF AN APPLICATION (Continued)

Item 3 – THIS IS APPLICATION 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 (except for some sub-site utilization records). Provide the physical address of the site to be designated as the main site.

Item 5 – INDIVIDUAL USERS AND THEIR TITLES

List the names and titles of the individuals who will be using the gauge or state that the Radiation Safety Officer (RSO) may designate users if the users have received the training as indicated in Item 12.

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.
- If multiple sites are requested, indicate the name(s) and qualifications (same as above) of the Site RSO and the telephone number(s) for each site.

Item 7 – RADIOACTIVE MATERIALS DATA

7a. List by isotope, such as cadmium 109 (Cd-109), iron 55 (Fe-55), etc.

7b. Identify the manufacturer's name(s) and the model number(s) of the sealed source(s).

7c. Indicate the maximum number of sealed sources of each isotope to be possessed. Include the activity for each sealed source and the total activity of each isotope to be possessed in a specific model device.

7d. Describe the use (lead in paint, metal alloy analysis, etc.) of the gauge and give the manufacturer's name and model number of the gauge.

Licensees are encouraged to perform frequent inventory checks to guard against loss or theft. A six-month inventory will be required by license condition to ensure accountability of the sources.

IV. CONTENTS OF AN APPLICATION (Continued)

Item 8 – FACILITIES

1. Describe the permanent storage facility for radioactive material, to include the following.
 - a. 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 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. Provide a diagram and description of the radioactive materials storage/use areas. Indicate its relation to and distance from occupied areas within the facility and adjacent areas that may be occupied.
 - 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.

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. Describe the applicant's position on radiation safety in relation to the work environment.
2. Radiation Safety Officer Duties. Explain the RSO's duties in the company with emphasis on overseeing the radiation safety program. Describe records of administration, radiation surveys, periodic field inspections, etc. that will be maintained by the RSO.

IV. CONTENTS OF AN APPLICATION (Continued)

3. Individual Monitoring Devices (if necessary). Individual personnel monitoring devices must be supplied to and worn by occupational workers likely to exceed 500 millirem in one year. If personnel monitoring devices are not used, you must justify this decision with sufficient documentation. 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).
4. Emergency Procedures. Describe the actions to be taken by the user when emergency situations involving radioactive material occur. These situations could involve the theft of the gauge, loss of control, an accident that damages or destroys the gauge, the loss or damage to the technician's individual monitoring device, or the accidental exposure of workers. Also, describe the actions to be taken by the RSO when emergency situations occur.
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; Utilization logs; Individual monitoring reports (if applicable); and Training.
6. Equipment Maintenance and Inspection Procedures. Describe routine maintenance and inspections to be performed on the gauge(s), indicating what items are to be checked, the documentation of and specific intervals for the maintenance and/or inspections to be performed.

Item 10 - RADIATION DETECTION INSTRUMENTATION

Survey instruments are not required.

Item 11 - LEAK TESTING

Sealed sources shall be leak tested every six months [25 TAC §289.201(g)]; describe the method to be used for leak testing.

Item 12 - TRAINING AND EXPERIENCE

Each user must successfully complete a radiation safety course approved by the department and must complete a period of on-the-job training (usually three to six months). Provide copies of the certificates that indicate successful completion of the course. The qualifications and training requirements for the RSO are the same as for a user. Applicants desiring to provide formal radiation safety training in-house should submit a detailed course outline, sample examinations, instructor name and qualifications.

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.

IV. CONTENTS OF AN APPLICATION (Continued)

Item 14 - FINANCIAL QUALIFICATION AND FINANCIAL ASSURANCE

Portable XRF Gauge users are not required to provide financial assurance. Complete all applicable areas on the form and mark the first box at the bottom 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.

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 operation 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 renewal 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. Send your amendment request to the Industrial Licensing Program at the following address: Texas Department of State Health Services, Radioactive Material Licensing – MC 2835, P.O. Box 149347, Austin, Texas 78714-9347.
5. You will receive your license amendment by mail.
6. 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.
7. 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.
8. 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.
9. 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 [§289.202(ccc)] or last leak test record.
10. 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 by regular mail.

VI. LICENSE AMENDMENT OR TERMINATION (Continued)

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.

VI. LICENSE AMENDMENT OR TERMINATION (Continued)

- d. Documentation of radioactive material disposition and radiation surveys (or current leak tests) required by 25 TAC (I)(4)(C).
 - 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