Texas Department of State Health Services
Radiation Safety Licensing Branch

REGULATORY GUIDE 2.6

GUIDE FOR THE PREPARATION OF RADIOACTIVE MATERIAL LICENSE APPLICATIONS FOR THE USE OF GAS CHROMATOGRAPH DETECTORS

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 agency, topics of interest about radiation, and links to other radiation-related web sites.

The agency website 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:

1. Industrial Licensing Program - for questions regarding the regulation of gas chromatograph devices and the application for radioactive material license and any related correspondence.

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 fixed gauge 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 downloaded from the DSHS Internet site. 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. License Fees

A. A fee must be submitted with each new application. Refer to §289.204 to determine the fee that should accompany the application. 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.

B. 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, 2005, 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.

C. 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.

IV. Licensing Process

A. <u>Completing the Application</u>

1. Submit BRC Form 252-2, "Application for Radioactive Material License," for the use of gas chromatograph devices.

2. Complete all items on the application in sufficient detail to allow the licensing reviewers to make a complete evaluation of the program for use of radioactive material in gas chromatograph 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 on 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.

Items 1-15 of the application are discussed below:

Item 1 - NAME AND MAILING ADDRESS OF APPLICANT: Indicate the name and mailing address of the applicant. The applicant should be the corporation or other legal entity applying for the license to possess and use the radioactive material. 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 each location of use and/or storage by street address and city, or provide a descriptive address (such as five miles east of FM Road 14 on Texas Highway 10, Anytown, Texas) that will allow the Agency to easily locate the applicant's facility. A post office box address alone is not acceptable. Also, indicate whether the radioactive material will be used at temporary job sites throughout Texas.

Item 3 - Self-explanatory.

Item 4 - LOCATION WHERE RECORDS WILL BE KEPT: Indicate where records are to be maintained. If multiple storage sites are being requested, records for each site's operation must be maintained at that site and at the main Texas facility location.

Item 5 - INDIVIDUAL USERS AND THEIR TITLES: List the names and titles of the individuals who will be using the detector. 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 the agency rules, and is the primary contact with the agency 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:

1. The RSO's training and experience with radioactive materials and in the field of

radiation safety.

2. Indicate the name of the RSO and telephone number(s), FAX number(s), and electronic mail address(es) where the RSO may be contacted.
3. 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:

1. 7a. List by isotope, such as nickel 63 (Ni-63), tritium (H-3), etc.
2. 7b. Give the manufacturer's name(s) and the model number(s) of the electron capture detector(s) or sealed source(s).
3. 7c. Indicate the maximum number of millicuries of each isotope to be possessed. Include the total activity for material in each model gas chromatograph in storage or use.
4. 7d. Describe the use of the detector cell and/or give the manufacturer's name and model number of the gas chromatograph.

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

Item_8 - FACILITIES: If the gas chromatograph contains tritium, the facility description should indicate that the unit is exhausted to the outside, to a laboratory hood that exhausts to the outside, or back into the process stream. When a detector cell is stored outside of the gas chromatograph, describe the conditions and location of storage, and the labeling and safety precautions. Indicate security precautions to be taken to prevent theft or unauthorized use.

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.
3. Individual Monitoring Devices (if necessary). Individual personnel monitoring requirements are in accordance with §289.202(q). Individual monitoring devices shall meet the requirements of §289.202(p)(3).
6. 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.
7. 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:
   a. receipt, transfer, and disposal;
   b. leak tests;
   c. utilization logs;
   d. individual monitoring reports, if applicable; and
   e. training.

8. 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. If leak tests are to be analyzed by a leak test service firm, the firm should be authorized by the Agency, the U. S. Nuclear Regulatory Commission, or another Agreement State.

Item 12 - TRAINING AND EXPERIENCE: Qualifications and training requirements for users of this type of device are minimal. A statement must be made by the applicant indicating that each user reads and understands the operating manual before using the device. If the RSO is to designate users, indicate how the RSO will document that each user has read and understands the owner's manual. This documentation must be available for inspection by the Agency.

Item 13 - WASTE DISPOSAL: The applicant must describe how the radioactive material will be disposed of when it is no longer needed or used.

Item 14 - FINANCIAL QUALIFICATION AND FINANCIAL ASSURANCE: 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. Gas chromatograph users usually are not required to provide financial assurance.

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.

As a part of an application for new license or renewal of an existing license you must submit a completed and signed BRC Form 252-1 Business Information Form.

COMPLETING THE APPLICATION FOR RENEWAL: Because of the advances in radiation safety techniques, the 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.

SUBMITTING A REQUEST FOR LICENSE AMENDMENT OR LICENSE TERMINATION

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 to the Industrial Licensing Program.
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 agency, 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 agency will accept facsimile transmissions as a formal request for amendment.

Please limit facsimiles to no more than ten pages, thus originals need **NOT** be sent by regular mail.

11. To terminate your license, the agency requires the following.
    a. Request should specify that you want to **terminate** the license.
    b. Copies of surveys (or current leak tests) required by §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 §289.252(l)(4)(C).
    e. All Notices of Violation shall be resolved through the DSHS Policy/Standards/ Quality Assurance's Radiation Group.
12. 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.
13. Always address license amendment or license termination requests to:

Texas Department of State Health Services
Radiation Safety Licensing Branch
Attn: Industrial Licensing Program
1100 West 49th Street
Austin, Texas 78756-3189