



Texas Department of State Health Services Radiation Safety Licensing Branch

Regulatory Guide 8.1

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GUIDE FOR SUBMITTING APPLICATIONS OR AMENDMENT REQUESTS DUE TO CHANGES IN LICENSED LEGAL ENTITY

I. INTRODUCTION

This guide describes the general conditions that may require either issuance of a new radioactive material license or amendment to an existing license due to a change in the licensed legal entity (e.g., sale, merger, reorganization or transfer of certain operations or assets of a corporation, partnership, or sole proprietorship). Each situation will be evaluated on a case-by-case basis by the Department of State Health Services (DSHS), Radiation Safety Licensing Branch in accordance with the following guidance.

In accordance with rule, Title 25 Texas Administrative Code (TAC) §289.252(x)(2), transfer of licenses to other persons is prohibited unless the agency shall, after securing full information, find that the transfer is in accordance with agency rules and orders and shall give its consent in writing. DSHS shall also be contacted at least 30 days prior to a licensee relinquishing control of a site. If an application for a new license is required, application forms and regulatory guides for specific types of licenses are available at DSHS's website: (<http://www.dshs.state.tx.us/radiation/>)

II. GUIDANCE

The licensed legal entity is identified by DSHS based on the unique filing number generated by the Texas Secretary of State's (SOS) Office (www.sos.texas.state.tx). For a Texas entity, the filing number is issued when the entity files to create the business. For an out-of-state entity, the filing number is issued when the entity registers to transact business in Texas. After the initial SOS filing, some changes may be made to the entity that do not result in a new legal entity being formed. Examples are a change in its name or organizational changes in officers or registered agent. However, some changes (often involving a change in structure or ownership) are significant enough that a new legal entity is formed resulting in a new filing number. If the SOS's office issues a new filing number, then a new legal entity exists and the new entity must apply for a new radioactive material license.

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. GUIDANCE

A. **DSHS Licensed Entity Retains SOS Filing Number**

When the change to the legal entity is minor and the SOS filing number is unchanged an amendment to the license may still be necessary. These amendment requests must include an updated RC Form 252-1 (Business Information Form). License amendment is necessary if any of the following occur:

1. **Name Change / Change in Officers** If the business name associated with the Texas Secretary of State's file number has been amended or if the officers change, the licensee must submit an amendment request with an explanation of the change. An updated RC Form 252-1 (Business Information Form) must be included with the request. To ensure compliance with 25 TAC §289.252(x)(4), a name change must be reported to the department within 15 calendar days of the day it occurs;
2. **Assumed Name / Doing Business As (DBA) Name** If an assumed name has been added to the Texas Secretary of State filing and the licensee wants to perform licensed activities under that name, the licensee must submit a name change amendment request and an updated RC Form 252-1 (Business Information Form). For an assumed name used state-wide the name must be filed with the Texas Secretary of State. For businesses operating in only one Texas county, a DBA registration with the county is sufficient.

Please note that if there is a change of ownership the licensee may continue to operate under the existing license provided:

- the licensed legal entity remains in existence and the license status current,
- the entity's status with the Texas Secretary of State remains current,
- the conditions of the existing license are met,
- the current RSO is retained,
- the Operating, Safety and Emergency Procedures remain in effect, and
- no changes are made to the existing facility(s) storage and use areas.

B. **DSHS Licensed Entity Relinquishes Control to an Entity with a Different SOS Filing Number**

When a licensed legal entity's operations, facility and/or radioactive material are acquired by another entity, or the licensed legal entity changes sufficiently to result in the creation of a new entity, the new entity must apply for a new radioactive material license. It does not matter if the change is due to a sale, merger, reorganization, or any other manner of change to the licensed legal entity. The key factor requiring a new license is that a new legal entity with a new SOS filing number now has a need to possess and use radioactive material.

1. The new entity must submit the following:
 - a. an application for radioactive material license (RC Form 252-2 or RC Form 252-2a as appropriate), per 25 TAC §289.252(d)
 - b. a Business Information Form (RC Form 252-1)
 - c. Operating, Safety and Emergency Procedures, and
 - d. the appropriate two year fee payment.

II. GUIDANCE

B. Change in Legally Licensed Entity (Continued)

2. The previous licensee must submit:
 - a. a signed request (e.g. a letter) for license termination within 60 days of ceasing principal activities per TAC §289.252(y)(4)(B),
 - b. documentation of transfer of the radioactive material, and
 - c. a closeout survey for the facility. For a licensee possessing only sealed sources, leak test certificates for all sources may be submitted in place of a survey.

III. INTERIM OPERATIONS

Title 25 TAC §289.252(a)(2)(A) prohibits the possession and use of radioactive material without a radioactive material license. If strictly applied, an unlicensed entity in control of newly transferred radioactive material would be required to cease all operations involving radioactive material and divest itself of the radioactive material until licensed.

Recognizing, however, that requiring a company to cease operations while applying for a new radioactive material license could lead to financial hardship and in the case of medical use licenses, could threaten patient health, DSHS has developed the following policies and procedures to allow interim operations during a change in licensed legal entity. This authorization must be granted in writing in accordance with TAC §289.252(x)(2) subject to certain limitations. A few examples of requirements for conducting interim operations following a change in legal entity follow.

A. A DSHS licensed entity has a legal relationship with a new controlling entity that needs to take possession of and/or use their radioactive material. The relationship may be the result of a sale, merger, reorganization, or other legal agreement that results in both parties being agreeable to keeping the existing DSHS license in place on an interim basis.

1. The licensed entity is allowed to operate under its existing license during the interim period provided all of the following conditions are met;
 - a. the licensed entity submits a letter at least 30 days before relinquishing control explaining the pending change in entity, the legal business relationship between the entities, and the nature of the agreement to operate under the existing license,
 - b. the new entity submits a completed application for radioactive material license within 30 calendar days of the date the new entity assumes control,
 - c. the new entity responds to all requests for additional information within 30 days of the date of the information request,
 - d. the licensed entity remains in existence,
 - e. operations are officially conducted under the licensed entity's name until the new license is issued,
 - f. the licensed entity's status with the Texas Secretary of State remains current,
 - g. all conditions of the license are met,
 - h. the Radiation Safety Officer (RSO) is unchanged,
 - i. the Operating, Safety and Emergency Procedures remain in effect, and
 - j. no changes are made to the existing facility(s) storage and use areas.

III. INTERIM OPERATIONS

A. (Continued)

- 2 If any of the above conditions cannot be met, the new entity may still petition DSHS to continue operations under the existing license and entity name. The request must be in writing and contain supporting documentation regarding alternative means of complying with the intent of the above conditions.

DSHS will provide consent in writing if the above submissions are accepted. The original licensed entity will need to submit a request for license termination after the new entity is issued a license. If the new entity fails to timely comply with the requirements in either III.A.1. b and c they may be fined for possessing or using radioactive materials without a license and the radioactive material in their possession impounded pending issuance of the new license. If multiple conditions in III.A.1. are not met, the new entity will be required to have a new license prior to possessing or using radioactive material and cannot conduct interim operations.

B. The new controlling entity has an existing Texas radioactive material license, has no on-going legal relationship with the previously licensed entity or does otherwise not conduct interim operations under III.A.

1. As a permanent licensing solution the new entity may submit an amendment request to add a newly acquired site to their radioactive material license.
- 2 If a new license for the new site is required either due to DSHS policy or policies of the new controlling entity, the new entity may request that DSHS allow it to possess and/or use radioactive material at the new location temporarily as a sub-site on the existing Texas license provided;
 - a. Prior to taking possession of or using the newly acquired material the new controlling entity submits a temporary site addition amendment request,
 - b. the new entity applies for a new license within 30 calendar days of when it acquires the new radioactive material,
 - c. the new entity responds to all requests for additional information within 30 days of the date of any information request,
 - d. the new entity must be authorized for the same use(s) on its existing license,
 - e. the new entity names a site RSO if the RSO on the existing license is not located close enough (e.g. less than a one hour drive) or is otherwise unable to fulfill their responsibilities at a the new site,
 - f. the new entity's existing license conditions are met,
 - g. the new entity's Operating, Safety and Emergency Procedures must remain in effect, and
 - h. no changes are made to the existing facility(s) storage and use areas.
- 3 If any of the above conditions in III.B.2. cannot be met and a new license is required, the new controlling entity may request to operate under its license on an interim basis by submitting in writing supporting documentation regarding alternative means of complying with the intent of the above conditions.

III. INTERIM OPERATIONS

B. (Continued)

If the request in III.B.2. or 3. is accepted DSHS will issue an amendment to the new entity's radioactive material license authorizing the temporary possession and/or use of radioactive material at the new site. If not accepted the new entity must be issued a new radioactive material license prior to possessing or using the newly acquired radioactive material.

If the new entity fails to comply with any conditions III.B.2.a through c, it may be cited for possessing and using radioactive materials without a license, and is subject to being fined and having radioactive material in its possession impounded pending issuance of the new license. NRC and other agreement state licensees may request reciprocity to operate in Texas and treat a newly acquired site as a temporary job site under their out-of-state license, provided they comply with the conditions in III.B.2.b. through h and receive written authorization from DSHS.

The original licensed entity must submit a request for license termination within 60 days of ceasing activities authorized on its license per 25 TAC §289.252(y)(4)(B).

C. The new controlling entity does not possess a radioactive material license and has no on-going legal relationship with the previously licensed entity.

If the new controlling entity is unlicensed, it must apply for and be issued a radioactive material license prior to possessing or using radioactive material. If the new entity is unable to immediately divest itself of the radioactive material it may make a written request to DSHS asking for written authorization to securely store the material in the interim.

In cases of extreme hardship or threat to health and safety, the new entity may petition DSHS to allow it to conduct operations under an interim license issued to the new entity, containing the same terms as the previous license at the facility. The written request must provide detail of the hardship and/or threat to health and safety, include a completed Business Information Form (RC Form 252-1) and commit to or explain how the following conditions will be met:

1. a completed application for radioactive material license must be submitted within 30 calendar days after the new entity acquires the licensed entity,
2. all requests for additional information must be responded to within 30 days of the date of the information request,
3. all conditions of the previous entity's license must be met,
4. the Radiation Safety Officer (RSO) must not change,
5. authorized users must not change,
6. the previous licensee's Operating, Safety and Emergency Procedures must remain in effect, and
7. no changes are made to the existing facility(s) storage and use areas.

III. INTERIM OPERATIONS

C. (Continued)

If the request is granted, DSHS will issue a license based on the previous license that expires after a short term (e.g. 90 days). If the new entity fails to comply with the 30-day time requirements in III.C.1. or 2., it may be fined for possessing and/or using radioactive materials without a license, and may have radioactive material in its possession impounded pending issuance of a new license.

The original licensed entity must submit a request for license termination within 60 days of ceasing activities authorized on their license per 25 TAC §289.252(y)(4)(B).

IV. NOTES

- A. **Signatures** All statements and commitments must be signed by an authorized management representative (i.e., Owner, CEO, President, authorized RSO, etc...) of the appropriate legal entity (i.e. corporation, partnership, or sole proprietorship).
- B. **Fees** By rule, 25 TAC §289.204(d)(1), licensing fees are non-refundable. New license applicants are required to submit a full two year fee. If a fee is paid by a new entity on behalf of a previously licensed entity, and notification can be made to DSHS within 30 days of payment, the fee payment can be applied toward a new license application.

For additional information please call (512) 834-6688 press "0" and ask to speak to the Program Coordinator of the Medical and Academic Licensing Program, the Program Coordinator of the Industrial Licensing Program, or the Program Coordinator of the Advanced Technology Licensing Program in the Radioactive Material Licensing Branch, whichever is appropriate to your activities.