

ADOPTED RULES

Adopted rules include new rules, amendments to existing rules, and repeals of existing rules. A rule adopted by a state agency takes effect 20 days after the date on which it is filed with the Secretary of State unless a later date is required by statute or specified in the rule (Government Code, §2001.036). If a rule is adopted without change to the text of the proposed rule, then the *Texas Register* does not republish the rule text here. If a rule is adopted with change to the text of the proposed rule, then the final rule text is included here. The final rule text will appear in the Texas Administrative Code on the effective date.

TITLE 1. ADMINISTRATION

PART 12. COMMISSION ON STATE EMERGENCY COMMUNICATIONS

CHAPTER 251. 9-1-1 SERVICE--STANDARDS

1 TAC §251.16

The Commission on State Emergency Communications (CSEC) adopts new §251.16, relating to direct access to 9-1-1 service from a telephone system including a multi-line telephone system (telephone system), with changes to the proposed text published in the October 30, 2015, issue of the *Texas Register* (40 TexReg 7503). CSEC has determined that changes to the proposed text do not require re-proposing the rule as the changes do not (1) change the nature or scope of the rule so much that it could be deemed a different rule; (2) affect individuals who would not have been impacted by the rule as proposed; or (3) impose more stringent requirements for compliance.

CSEC received comments on the proposed rule from the Texas Hotel & Lodging Association (TH&LA) and the Texas 9-1-1 Alliance (the Alliance). As a result of the Alliance's comments, CSEC adopts proposed new §251.16 with non-substantive changes as described herein.

TH&LA Comment: TH&LA commended the Commission's efforts in implementing Kari's Law and urges adoption of the rule as proposed.

CSEC Response: No response required. CSEC appreciates the support and efforts of TH&LA in helping to address the issue of directly accessing 9-1-1 service via a telephone system.

Alliance Comment: The Alliance supports adoption of the rule and proposes two changes to the rule as published. First, that the text "on or" in subsection (c) and (d)(7) regarding the placement of the instructional sticker be clarified to "on and/or." Second, that the website link in subsection (e) for receipt of waiver requests be changed from www.csec.texas.gov/TexasKariLaw to a statewide website link such as Texas911.org.

CSEC Response: CSEC concurs with the Alliance's comments. CSEC makes non-substantive changes to the published text of subsections (c) and (d)(7) to clarify that the instructional sticker must be placed adjacent to a non-compliant telephone handset and, optionally, may also be placed on the handset. CSEC makes non-substantive changes to the published text of subsection (e) to change the URL for the website and to add an e-mail and regular mail address for the submission of waiver request affidavits.

The new rule is adopted pursuant to Texas Health and Safety Code §771A.001(f) and §771.051.

No other statute, article, or code is affected by the adoption.

§251.16. *Direct Access to 9-1-1 Service.*

(a) Purpose. The purpose of this rule is to facilitate the implementation of Texas Health and Safety Code Chapter 771A ("Kari's Law") requiring telephone systems that provide outbound dialing capacity to be configured to provide direct access to 9-1-1 service and, in instances where no hardware changes are necessary, to provide notification of a 9-1-1 call to a central location on the site of the residential or business facility from which a 9-1-1 call is made using a telephone system.

(b) Definitions. For the purposes of this rule:

(1) "9-1-1 service" means a communications service that connects users to a public safety answering point through a 9-1-1 system.

(2) "Additional location" means an optional location, other than a central location, that receives notification of a 9-1-1 call that should be staffed 24x7 with personnel that can assist emergency first responders in accessing the residential or business facility from which a 9-1-1 call is made and determining the location of the 9-1-1 call, e.g., Campus Police, Security Office.

(3) "Business service" means a telecommunications or communications service provided a customer where the use is primarily of a business, professional, institutional, or otherwise occupational nature.

(4) "Business service user" means a user of business service that provides telecommunications or communications service, including 9-1-1 service, to end users through a publicly or privately owned or controlled telephone switch. Business service user includes a "governmental body" as defined in §552.003, Government Code, including an institution of higher education.

(5) "Central location" means a designated location on the site of a residential or business facility from which a 9-1-1 call is made that receives notification of the 9-1-1 call. A central location is not required to have a person available at the location to receive or respond to the notification.

(6) "Commission" means the Commission on State Emergency Communications.

(7) "Internet Protocol enabled service" or "IP" has the meaning assigned by §51.002, Texas Utilities Code.

(8) "Local exchange access line" or "Equivalent local exchange access line" has the meaning assigned in Commission Rule 255.4 (Title 1, Part 12 Texas Admin. Code, §255.4).

(9) "Notification" refers to a telephone system feature that can send notice to a central location and optional additional location that a 9-1-1 call has been made. Common notifications include "screen pops" with audible alarms for security desk computers using a client application, text messages for smartphones, and email for administra-

tors. Where feasible, notification should provide the telephone number or extension and location information of the telephone system handset from which the 9-1-1 call is made.

(10) "Telephone switch" refers to the function of switching inbound and outbound calls in order to allow multiple end-users to share a defined number of local exchange access lines or equivalent local exchange access line.

(11) "Telephone system" refers to a legacy system, or equivalent system using Internet Protocol enabled service, comprised of common control units, interconnected telephone or handsets, control hardware and software, and adjunct systems that allow for advanced features such as call handling and transferring, conference calling, call metering and accounting, private and shared voice message boxes, direct inward/outward dialing. A telephone system, commonly referred to as a "multi-line telephone system" or MLTS, includes network and premises based systems such as Centrex and VoIP, as well as private branch exchange (PBX), Hybrid, and Key Telephone Systems (as classified by the Federal Communications Commission under Part 68 of Title 47, Code of Federal Regulations) and includes systems used, owned, or leased by governmental agencies and political subdivisions, for-profit businesses, and non-profit entities.

(12) Any term not expressly defined in this rule, has the meaning assigned in Commission Rule 252.7, Definitions.

(c) A business service user that owns or controls a telephone system that provides outbound dialing capacity or access shall configure the telephone system to allow a person initiating a 9-1-1 call on the system to directly access 9-1-1 service by dialing in order the digits 9, 1, and 1 without an additional code, digit, prefix, postfix, or trunk-access code. All non-compliant telephone handsets that provide outbound dialing capacity or access must have immediately adjacent to, and optionally on, the telephone the instructional sticker required in subsection (d)(7).

(d) A business service user shall be granted a one-year waiver (September 1 - August 31) of the requirements of Kari's Law and this rule upon submission of an affidavit not later than September 1 of each year that provides:

- (1) name (legal and any D/B/A), address, and contact information of the business service user;
- (2) address of all locations within Texas served by a non-complaint telephone system;
- (3) a narrative of efforts demonstrating a good faith attempt to reprogram or replace non-compliant telephone systems;
- (4) a statement that compliance with this rule is unduly and unreasonably cost prohibitive;
- (5) the manufacturer and model number of each non-compliant telephone system and the estimated costs to reprogram or replace each system;
- (6) a projected date for compliance with Kari's Law and this rule; and
- (7) confirmation that the business service user agrees to or has placed an instructional sticker immediately adjacent to, and optionally on, each non-compliant telephone handset instructing the user how to access 9-1-1 service. The instructional sticker must be printed in at least 16-point boldface type, in a contrasting color using a font that is easily readable, and is written in English and Spanish.

(e) A business service user's waiver request affidavit may be submitted electronically to <http://texas911.org/karislaw/> or mailed to the appropriate address provided in the website link.

(f) A business service user that provides residential or business facilities and owns or controls a telephone system that provides outbound dialing capacity or access shall configure the telephone system to provide notification when a person within a residential or business facility dials 9-1-1 if the telephone system is able to be configured to provide the notification without an improvement to the system's hardware. The notification requirement is separate from and in addition to the requirement in Texas law that "9-1-1 service" connects a 9-1-1 caller to the public safety answering point designated for the area from which the call is made.

(g) A business service user in compliance with this rule is deemed a "third party or other entity involved in the providing of 9-1-1 service" as that term is used to limit liability in §771.053, Texas Health and Safety Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Patrick Tyler

General Counsel

Commission on State Emergency Communications

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For further information, please call: (512) 305-6922



TITLE 13. CULTURAL RESOURCES

PART 2. TEXAS HISTORICAL COMMISSION

CHAPTER 26. PRACTICE AND PROCEDURE

The Texas Historical Commission (THC) adopts amendments to Chapter 26, concerning Rules of Practice and Procedure, §26.3 related to Definitions; §26.14 related to Issuance and Restrictions of Archeological Permits; §26.20 related to Application for Historic Buildings and Structures Permits; §26.21 related to Issuance and Restriction of Historic Buildings and Structures Permits; and §26.22 related to Historic Buildings and Structures Permit Categories, without changes to the text as published in the November 20, 2015 issue of the *Texas Register* (40 TexReg 8082). The amendments implement §2005.003 of the Texas Government Code, related to Permit Processing Periods, and offer minor clarification regarding definitions and when certain permit types are needed.

The permit applications for Archeology and Historic Buildings and Structures generally follow similar review processes, but there are some significant differences due to the types of permits and the nature of the proposed work for different cultural resources. An example is that a Historic Buildings and Structures Permit may be issued for restoration or demolition of a structure, but Archeological Permits are not issued for restoration or demolition. Conversely, Archeological Permits may be issued for intensive survey or monitoring of a known or suspected archeological site, but Historic Buildings and Structures Permits are not issued for intensive survey or monitoring. Consequently, it is necessary and appropriate for the proposed rules to estab-

lish different timelines for processing of the Archeological Permit applications versus Historic Buildings and Structures Permit applications.

When a permit application is received, the THC may take any of the following actions:

- (1) Accept the permit application and issue the permit;
- (2) Request more project information from the permit applicant;
- (3) Request a revised scope of work or research design from the permit applicant;
- (4) Refer the application to the Antiquities Advisory Board for consideration; or
- (5) Deny issuing the permit.

If the THC requests more information or revisions from a permit applicant, the permit processing time starts upon receipt of the complete permit application.

Some examples of cases where a permit might be denied would include:

- (1) A permit application is submitted by someone who does not meet the professional qualifications listed in §26.4;
- (2) An Archeological Permit application is submitted for survey work, but THC determines (or previously determined) that the survey is not warranted;
- (3) An Archeological Permit application is submitted by a project sponsor or agency because they mistakenly believed the permit was for the development project (rather than an archeological investigation), or they believed that the permit application was a required part of the initial project review inquiry;
- (4) A Historic Buildings and Structures Permit application is submitted for routine maintenance that does not require a permit, for work outside the designated State Antiquities Landmark boundaries, or for a property that is not designated as a landmark; or
- (5) A Historic Buildings and Structures Permit application is submitted for demolition or other proposed work that the THC determines is inappropriate and does not meet the Secretary of the Interior's Standards for the Treatment of Historic Properties.

Section 26.3(63) is the definition of State Antiquities Landmark, referred to throughout the rules as a landmark. The proposed revision clarifies what may be considered a landmark, in addition to those officially designated by the THC. The phrase "eligible to be designated as a landmark" is replaced by a more precise reference to the interim protection of properties nominated and determined eligible for designation, as described in §26.8(d).

Section 26.14 describes the process for issuance of Archeological Permits. Proposed revisions to §26.14(a) provide additional details regarding the process by which the commission reviews and issues permits. Commission staff will notify the applicant of any additional information needed to complete the review within 30 days of receipt of the permit application. Within 30 days of receipt of a complete application, the commission will take action on the permit application, as described above.

The procedures for submission of applications for Archeological Permits are consistent with the Antiquities Code of Texas, §191.054 and §191.093, Texas Natural Resources Code and allow sufficient time for proposals to receive review by commission staff and approval by the director of the Archeology Division. Archeological Permits are considered granted upon issuance of

the permit number, and the permit itself may take additional time to process. For Archeological Permits issued in fiscal year 2015, between September 1, 2014 and August 31, 2015, the processing time for permits ranged between 1 and 14 days, with a median permit processing time of one day from receipt of the permit application.

Section 26.20 describes the application procedures for Historic Buildings and Structures Permits. No changes are proposed to the timelines or procedures established in this section. The commission completes its review of an initial notification of proposed work to a State Antiquities Landmark within 30 days of receipt and specifies in its response if a formal permit application is needed. A permit application should be submitted at least 60 days prior to the commencement of work or issuance of bid documents. Section 26.20(a)(2) is revised in a similar manner to §26.3, as described above. Information on the timing of permit issuance has moved from §26.20(a)(9) to §26.21. Section 26.20(a)(9) is also revised to indicate that, if contract documents are issued prior to receiving a permit, the THC will not be responsible for any delays or costs associated with changes needed to meet the Secretary of the Interior's Standards for the Treatment of Historic Properties.

Section 26.21 describes the process for issuance of Historic Buildings and Structures Permits. Proposed revisions to §26.21(a) provide additional details regarding the process by which the commission reviews and issues permits. While commission staff will notify an applicant promptly if there are obvious omissions in the permit application and supporting material, thorough review of plans and specifications may be necessary to determine if additional information is needed to issue the permit. Such information could include additional drawings, construction details, or product information. The commission will notify the applicant of any additional information needed to complete the review within 30 days of receipt of the permit application. Within 60 days of receipt of a complete application, the commission will take action on the permit application, as described above.

The procedures for submission of applications for Historic Buildings and Structures Permits are consistent with the Antiquities Code of Texas, §191.054 and §191.093, Texas Natural Resources Code and allow sufficient time for proposals to receive review by commission staff and approval by the director of the Division of Architecture and the executive director of the commission. For Historic Buildings and Structures Permits issued in fiscal year 2015, between September 1, 2014 and August 31, 2015, the processing time for permits ranged between 1 and 70 days, with a median permit processing time of 22 days from receipt of the permit application. During this period, 99% of all permits were issued within 60 days.

Section 26.22 lists and describes the Historic Buildings and Structures permit categories. Additional language in §26.22(4) and (9) describes the limited circumstances in which a Historic Buildings and Structures permit could be required for a landmark that is significant as an archeological site. In particular, Division of Architecture staff review permits for reconstruction of missing features to ensure the design is accurate and meets the Secretary of the Interior's Standards for Reconstruction. In some instances, architectural review of new construction projects at archeological sites may also be appropriate.

Mark Wolfe, Executive Director, has determined that for the first five-year period the new rules are in effect there will be no fiscal

implications for state or local government as a result of enforcing or administering the rule.

Mr. Wolfe has also determined that for each year of the first five year period these new rules are in effect the public benefit anticipated will be an increased efficiency and effectiveness in the implementation of the Antiquities Code of Texas. Additionally, Mr. Wolfe has determined that there will be no effect on small businesses.

No comments were received regarding adoption of the amendments.

SUBCHAPTER A. GENERAL PROVISIONS

13 TAC §26.3

Adoption of these amendments is authorized under §§442.005(b), 442.005(q), and 442.005(r), Texas Government Code; §191.052, Texas Natural Resources Code; and §2005.003, Texas Government Code, which provide the Texas Historical Commission with the authority to promulgate rules and conditions to reasonably effect the purposes of this chapter. No other statutes, articles, or codes are affected by these sections.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Mark Wolfe

Executive Director

Texas Historical Commission

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For further information, please call: (512) 463-1858



SUBCHAPTER C. ARCHEOLOGY

13 TAC §26.14

Adoption of these amendments is authorized under §§442.005(b), 442.005(q), and 442.005(r), Texas Government Code; §191.052, Texas Natural Resources Code; and §2005.003, Texas Government Code, which provide the Texas Historical Commission with the authority to promulgate rules and conditions to reasonably effect the purposes of this chapter. No other statutes, articles, or codes are affected by these sections.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Mark Wolfe

Executive Director

Texas Historical Commission

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For further information, please call: (512) 463-1858



SUBCHAPTER D. HISTORIC BUILDINGS AND STRUCTURES

13 TAC §§26.20 - 26.22

Adoption of these amendments is authorized under §§442.005(b), 442.005(q), and 442.005(r), Texas Government Code; §191.052, Texas Natural Resources Code; and §2005.003, Texas Government Code, which provide the Texas Historical Commission with the authority to promulgate rules and conditions to reasonably effect the purposes of this chapter. No other statutes, articles, or codes are affected by these sections.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Mark Wolfe

Executive Director

Texas Historical Commission

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For further information, please call: (512) 463-1858



TITLE 19. EDUCATION

PART 2. TEXAS EDUCATION AGENCY

CHAPTER 97. PLANNING AND ACCOUNTABILITY

SUBCHAPTER EE. ACCREDITATION

STATUS, STANDARDS, AND SANCTIONS

19 TAC §97.1073

The Texas Education Agency adopts an amendment to §97.1073, concerning accreditation status, standards, and sanctions. The amendment is adopted without changes to the proposed text as published in the December 25, 2015 issue of the *Texas Register* (40 TexReg 9430) and will not be republished. The section establishes criteria for the appointment of a monitor, conservator, management team, or board of managers. The adopted amendment modifies the rule to reflect changes made by House Bill (HB) 1842, 84th Texas Legislature, Regular Session, 2015, to the Texas Education Code (TEC), §39.107 and §39.112, regarding appointed boards of managers.

REASONED JUSTIFICATION. In response to HB 1, 79th Texas Legislature, Third Called Session, 2006, the commissioner exer-

cised rulemaking authority to adopt rules for accreditation standards and sanctions in 19 TAC Chapter 97, Subchapter EE, effective January 6, 2008. Included in this subchapter is 19 TAC §97.1073, which addresses the establishment of criteria for the appointment of a monitor, conservator, management team, or board of managers. This rule was last amended effective February 5, 2015, to update references to statute and to other rules.

The adopted amendment to 19 TAC §97.1073, Appointment of Monitor, Conservator, or Board of Managers, modifies the rule to reflect changes made by HB 1842, 84th Texas Legislature, Regular Session, 2015, regarding appointed boards of managers, as follows.

Adopted new subsection (f) requires the commissioner to notify boards of managers and trustees when the appointment of a board of managers will expire no later than two years from the time of the appointment.

Adopted new subsection (g) requires a board of managers appointed to a district, during the period of its appointment, to order the election of members of the board of trustees of the district in accordance with applicable provisions of law. Adopted rule language specifies that elections for trustees with three-year terms must be ordered to be held annually, in accordance with the TEC, §11.059(b), and that elections for trustees with four-year terms must be ordered to be held biennially in accordance with the TEC, §11.059(c). Moreover, adopted new subsection (g) specifies the timeframe for the replacement of the board of managers by members elected to the school district board of trustees as well as describes the order, process, and sequence for the replacement.

Adopted new subsection (g) states that the commissioner may at any time replace a member of the board of managers and may expand their number commensurate with the number of members of the board of trustees at any time during the board of managers' appointment. Adopted new subsection (g) explains the powers and duties of an individual elected to a board of trustees and stipulates when those powers and duties will be counted for the purposes of constituting a quorum.

Finally, adopted new subsection (h) incorporates the statutory requirement that training in effective leadership strategies be provided to individuals appointed by the commissioner to a board of managers and, following the expiration of that board's appointment, to the board of trustees of the school district.

SUMMARY OF COMMENTS AND AGENCY RESPONSES. The public comment period on the proposal began December 25, 2015, and ended January 25, 2016. No public comments were received.

STATUTORY AUTHORITY. The amendment is adopted under the Texas Education Code (TEC), §39.107, as amended by House Bill (HB) 1842, 84th Texas Legislature, Regular Session, 2015, which authorizes the commissioner to order the appointment of a board of managers to govern a district as provided by TEC, §39.112(b), to replace a member of a board of managers appointed under TEC, §39.107, and to adopt rules necessary to implement that section, and TEC, §39.112, as amended by HBs 1842 and 3106, 84th Texas Legislature, Regular Session, 2015, which authorizes the commissioner to appoint boards of managers and provides a process by which board of managers members are appointed, removed, or replaced.

CROSS REFERENCE TO STATUTE. The amendment implements the Texas Education Code, §39.107, as amended by

House Bill (HB) 1842, 84th Texas Legislature, Regular Session, 2015, and §39.112, as amended by HBs 1842 and 3106, 84th Texas Legislature, Regular Session, 2015.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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TRD-201600615

Cristina De La Fuente-Valadez

Director, Rulemaking

Texas Education Agency

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For further information, please call: (512) 475-1497



TITLE 22. EXAMINING BOARDS

PART 23. TEXAS REAL ESTATE COMMISSION

CHAPTER 535. GENERAL PROVISIONS SUBCHAPTER R. REAL ESTATE INSPECTORS

22 TAC §535.210

The Texas Real Estate Commission (TREC) adopts amendments to 22 TAC §535.210 concerning Fees without changes to the proposed text as published in the November 20, 2015, issue of the *Texas Register* (40 TexReg 8094).

The amendment aligns the rule with statutory changes to Chapter 1101, Texas Occupations Code, adopted by the 84th Legislature, and rule changes to the education course delivery standards. A charge for providing certified copies of documents was also added.

The reasoned justification for the amendment is consistency with statutory provisions, greater consumer protection and clarity.

No comments were received on this proposal as published.

The amendments are adopted under Texas Occupations Code, §1101.151, which authorizes the Texas Real Estate Commission to adopt and enforce rules necessary to administer Chapters 1101 and 1102; and to establish standards of conduct and ethics for its license holders to fulfill the purposes of Chapters 1101 and 1102 and ensure compliance with Chapters 1101 and 1102.

The statutes affected by this amendment are Texas Occupations Code, Chapters 1101 and 1102. No other statute, code or article is affected by the amendment.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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TRD-201600616

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TITLE 25. HEALTH SERVICES

**PART 1. DEPARTMENT OF STATE
HEALTH SERVICES**

CHAPTER 289. RADIATION CONTROL

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), adopts amendments to §289.201 concerning general provisions for radioactive material; §289.202 concerning standards for protection against radiation from radioactive materials; §289.251 concerning exemptions, general licenses, and general license acknowledgements; §289.252 concerning licensing of radioactive material; and §289.257 concerning packaging and transportation of radioactive material. The amendment to §289.252 is adopted with changes to the proposed text as published in the November 20, 2015, issue of the *Texas Register* (40 TexReg 8106). Sections 289.201, 289.202, 289.251, and 289.257 are adopted without changes, and therefore, the sections will not be republished.

BACKGROUND AND PURPOSE

Amendments to §§289.201, 289.202, 289.251, 289.252, and 289.257 are necessary to comply with compatibility requirements of the United States Nuclear Regulatory Commission (NRC), to which Texas is subject as an Agreement State. The amendments are the result of the NRC's adoption of new and revised terminology and definitions, and regulatory standards and requirements for: the physical protection of Category 1 and Category 2 quantities of radioactive material; licensing termination under restricted conditions; exemptions for source material and other radioactive materials; general licenses for, and transfers of, small quantities of source material; other general licenses; sealed source or device evaluation; and packaging and transportation of radioactive material.

Subsequent to the terrorist events of September 11, 2001, the NRC issued orders for increased controls to certain licensees who were authorized to possess radioactive material in quantities of concern. The essential substance of those orders was added to federal regulation with the NRC's adoption of Part 37 to Title 10, Code of Federal Regulations (CFR), "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Those federal regulations provide the basis for compatible provisions in the proposed amendments relating to physical protection of Category 1 and Category 2 quantities of radioactive material.

Other amendments are made to §§289.201, 289.202, 289.251, 289.252, and 289.257 to clarify or include new or refined terminology, definitions, and requirements for: portable and mobile device utilization records; waste management; recordkeeping and reporting; specific terms and conditions of licenses; and the transportation and storage of radioactive material.

In addition, amendments to §§289.201, 289.202, 289.251, 289.252, and 289.257 include changes which update, correct, improve, or clarify: rule citation references; terminology; obsolete language; language consistency; units of measure; grammar; and minor typographical and formatting errors.

Government Code, §2001.039, requires that each state agency review and consider for re adoption each rule adopted by that agency. Sections 289.201, 289.202, 289.251, 289.252, and 289.257 have been reviewed and the department has determined that the reasons for adopting these sections continue to exist because rules on this subject are needed to protect public health and safety, to fulfill the department's statutory responsibilities as the state's Radiation Control Agency, and to comply with NRC compatibility requirements.

SECTION-BY-SECTION SUMMARY

To maintain rules that are compatible with the NRC, several new definitions are added to §289.201(b) to accommodate the new physical protection requirements for Category 1 and Category 2 quantities of radioactive material that are being incorporated into §289.252. The new definitions are designated as paragraphs (3), (8), (12), (14), (20), (21), (38), (45), (50), (67), (73), (75), (78), (109), (112), (113), (115), (128), (135), and (138). Subsequent definitions are renumbered.

Language is added to the definition of "becquerel" in new §289.201(b)(16) regarding commonly used multiples to create consistency with the comparable inclusion of common multiples in the definition of "curie."

In new §289.201(b)(19)(C) - (E), language is added to the definition of "byproduct material" to specify certain sources are considered to be byproduct material if the production, extraction, or conversion after extraction occurred "before, on, or after August 8, 2005," because, as an agreement state, Texas is subject to federal rule compatibility requirements for this definition.

The definition of effective dose equivalent in new §289.201(b)(42) corrects the equation " $H_E = \sum w_T H_T$ " to read " $H_E = \sum W_T H_T$ " to be consistent with the use of a similar equation in new §289.201(b)(27).

New definitions for "portable device" and "stationary device" are added as §289.201(b)(86) and (126) respectively, to define terminology currently used without definition in Chapter 289.

Current Figure: 25 TAC §289.201(b)(106)(B) is replaced with new Figure: 25 TAC §289.201(b)(124)(B) to reflect the new paragraph number due to the renumbering of paragraphs in the subsection.

Language is revised in new §289.201(b)(139) for the definition of "unrefined and unprocessed ore" to maintain rules that are compatible with NRC's rules.

A rule reference is revised in new §289.201(b)(143) to reflect the new paragraph number due to the renumbering of paragraphs in the subsection.

The term "licensing state" has been removed throughout §289.201 because the Suggested State Regulations for Control of Radiation (SSRCR), as written by the Conference of Radiation Control Program Directors, Inc. (CRCPD), no longer uses the terminology. Revisions are reflected in §289.201(g)(1)(B), (C), and (H); and (g)(3). The definition has not been removed since other references remain in sections to which these amendments have not yet been made.

References to "the agency," "the NRC," or "any agreement state," or the regulations of these agencies, are revised to be consistent with language used throughout the chapter. Revisions are made in §289.201(g)(1)(B), (C), and (H); and §289.201(g)(3).

The words "or equivalent regulations of the NRC or any agreement state" are added to §289.201(g)(1)(B) to recognize comparable NRC or agreement states, in the interest of promoting nationwide consistency in the control and regulation of radioactive materials.

References to "telegram" and "mailgram" are deleted in §289.201(k)(2) as these terms are obsolete and updated language is added to specify facsimile and other electronic media transmission as acceptable forms of transmission, in addition to mailing.

Other changes to §289.201 are made to correct, clarify, or improve phrasing, grammar, punctuation, and consistency within the section and/or chapter; to add, define, or remove acronyms or their definitions; to eliminate unnecessary or redundant verbiage; and to replace existing numerical references that were spelled out with their corresponding Arabic numerals.

Based upon requirements for compatibility with NRC regulations, the words "to ensure against recurrence" are added to §289.202(e)(4) relating to corrective action taken for exceeding the dose restraint limit.

References to "telegram" and "mailgram" are deleted in §289.202(j)(2)(C), (k)(5)(B), (ee)(4), and (xx)(3), as these terms are obsolete, and language is added to allow the referenced communication by other electronic media transmission, in addition to the other modes remaining in existing rule.

References to "the agency," "the NRC," or "any agreement state," or the regulations of these agencies, are revised to be consistent with language used throughout the chapter. Revisions are made in §289.202(p)(3)(A) and (ff)(2)(J).

The term "licensing state" has been removed from §289.202(p)(3)(A) because the SSRCR, as written by the CRCPD, no longer uses the terminology.

New §289.202(y)(4) and (5) are added regarding utilization record requirements for portable and mobile devices to be consistent with equivalent requirements for the industrial radiography, well logging, and generally licensed devices rule sections.

Language is added to §289.202(ff)(1)(C) and new (ff)(3) is added to the general requirements for waste management in order to reference requirements of the Texas Commission on Environmental Quality (TCEQ) and/or the Railroad Commission of Texas. Subsequent paragraphs are renumbered.

New §289.202(ff)(1)(E) is added to allow the transfer of residual radiopharmaceutical waste for decay in storage back to a person who originally manufactured, compounded, and supplied the radiopharmaceutical, and who otherwise meets TCEQ exemption requirements.

Rule reference citations are revised in §289.202(ff)(6) and (7) due to the renumbering of definitions in §289.201(b).

Recordkeeping language is revised in §289.202(p)(2), (mm)(2), (nn)(1), (nn)(3), (oo), and (pp) to reference that the record retention requirements are specified in the table in §289.202(ggg)(5),

and for use of language consistent with NRC compatibility requirements and within the chapter.

New §289.202(nn)(2) is added to clarify the required information for calibration records.

To clarify information required in reports of stolen, lost, or missing licensed sources of radiation, the words "the source and/or device manufacturer, model number and serial number" are added in §289.202(ww)(2)(A), (xx)(8)(A)(vi), (xx)(8)(B)(iii), (yy)(2)(B), and (bbb), and "dose limit exceeded" is added to §289.202(yy)(2)(B).

To ensure that department rules achieve the essential objectives of comparable NRC regulations, where required, new §289.202(ddd)(3), with subparagraphs (A) and (B), is added to address criteria for license termination under restricted conditions. Subsequent paragraphs are renumbered.

Due to the addition of §289.202(ddd)(3) and the renumbering of subsequent paragraphs, rule references in new §289.202(ddd)(4)(B), (5), and (5)(A)(ii) are revised.

New Figure: 25 TAC §289.202(ggg)(2)(F) replaces the figure with the same label in current rule to make corrections to the tables in that figure, which contain values for annual limits on intake (ALI) and derived air concentrations of radionuclides for occupational exposure; effluent concentrations; and concentrations for release to sanitary sewerage. The spelling of the word "monthly" is corrected to read "monthlly" in the figure's subheading, "Monthly Average Concentrations" under the Table III column heading, "Release to Sewers." The values in each of the radionuclides Nitrogen-13² (Atomic No. 7) and Oxygen-15² (Atomic No. 8) were moved over one column to the left to be correctly listed in Columns ("Col.") 2 and 3 of Table I. In the "Class" column for Titanium-44 (Atomic No. 22), the repeated word "nitrates" is removed as redundant. The term "LLI Wall" replaces "Bone Surf" for the oral ingestion ALI in Table I, Column ("Col.") 1, for Einsteinium-254m (Atomic No. 99), as the previous use of "Bone Surf" was incorrect.

In addition, Figure: 25 TAC §289.202(ggg)(2)(F) adds a superscripted "1" after the word "Submersion," in the column headed "Class," for the radionuclides Nitrogen-13 (Atomic No. 7) and Oxygen-15 (Atomic No. 8); a superscripted "1" is placed after the word "Submersion," in the column headed "Class," for the radionuclides Nitrogen-13 (Atomic No. 7) and Oxygen-15 (Atomic No. 8); a subscripted "3" is added in two places following "SrTiO" under the "Class" column for Strontium-80 (Atomic No. 38); and a subscripted "2" is added following "MoS" in the "Class" column for Molybdenum-90 (Atomic No. 42) and following "PuO" in two places in the "Class" column for Plutonium-234 (Atomic No. 94) to correct previous omissions.

The following are additional changes made in Figure: 25 TAC §289.202(ggg)(2)(F), due to typographical errors and/or omissions. In Table I, "Occupational Values," Column (labeled "Col.") 1, the stomach wall (labeled "St wall") oral ingestion ALI for Chlorine-38 (Atomic No. 17) is changed to read "(3E+4)"; in Table I, Column 1, the thyroid ALI for Iodine-120m (Atomic No. 53) is changed to read "(1E+4)," and, for Iodine-121 (Atomic No. 53), is changed to read "(3E+4)"; in Column 2, the thyroid ALI for Iodine-120 (Atomic No. 53) is changed to read "(1E+4)"; and in Table I, Column ("Col.") 2, the non-stochastic bone surface ALI for Gadolinium-148 (Atomic No. 64), Class D, for all compounds except those given for W, is corrected to read "8E-3," and the stochastic ALI is corrected to read "(2E-2)."

Further changes to Figure: 25 TAC §289.202(ggg)(2)(F) include the following corrections. In the "Class" column for Fluorine-18² (Atomic No. 9), "RB" is replaced with "Rb" to reflect the correct symbol for the element. In the "Radionuclide" column, an "m" is added to correct the entry for "Niobium-89² (66 min)" (Atomic Number 41), to now read Niobium-89m² which is correct. In the "Class" column for Uranium-230 (Atomic No. 92), the letter strings "D, UF, UOF, UO(NO)," "W, UO, UF, UCl," and "Y, UO, UO" are replaced with "D, UF, UO₂F₂, UO₂(NO₃)₂," "W, UO₃, UF₄, UCl₄," and "Y, UO₂, U₃O₈," respectively. In Table I, Column 2, the inhalation ALI for the "W" class of Uranium-238 (Atomic No. 92) is input to read "(8E-1)." In the radionuclide column for Neptunium-236 (22.5 h) (Atomic No. 93) an "m" is placed after "236." In addition, rule references are added in footnotes 2 and 3 and the "?" symbol in the final formula in numbered note 4 under "NOTES" is corrected to read "<."

Figure: 25 TAC §289.202(ggg)(4)(A)(iii)(V) is replaced to change "five years" to "5 years" for consistency of usage throughout the chapter.

The time requirements for the record keeping table in Figure: 25 TAC §289.202(ggg)(5) are revised to add the portable and mobile device utilization records category, which is a new requirement in §289.202(y)(5). The names of the record were changed for subsection (ll)(4) to delete the word "additional," and, for subsection (nn)(1), to replace "package surveys" with "package monitoring" to more accurately reflect the record types. In the "Specific Subsection" column, "(nn)(2)" is deleted and replaced with "(nn)(3)" as new paragraph (nn)(2) was added to the rule text, and the (B) is deleted in "(qq)(B)" to accurately reflect the subsection reference.

Further changes to Figure: 25 TAC §289.202(ggg)(5) include the replacement in the time interval column for (rr)(1) - (3) of the words "Update annually" with "Entries at no >1 year intervals, by April 30 each year" to accurately reflect the time interval required by rule for those records. In addition, the words "after the record was made" were added to the "Time Interval Required for Record Keeping" column for subsections (y)(5), (nn)(1), and (pp) for the entry addressing records used to prepare RC Form 202-2, in order to clearly reflect the date from which the time period is to be measured.

Language is revised in footnote f of Figure: 25 TAC §289.202(ggg)(6) to more clearly state the limits for the average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters. The last sentence of footnote f is added as it was inadvertently omitted in current rule. In addition, the word "shall" is substituted for the word "should" in footnotes a, e, f, and g so they will not be read as discretionary or merely advisory.

Figure: 25 TAC §289.202(ggg)(7) is revised to correct the annual generator disposal limit for Iodine-123 (I-123) in the table for concentration and activity limits of nuclides for disposal in a Type I municipal solid waste site or a hazardous waste facility.

Other changes to §289.202 are made to correct, clarify, or improve terminology, phrasing, grammar and usage, punctuation, and consistency within the section and/or chapter; to add, define, or remove acronyms or their definitions; to eliminate unnecessary or redundant verbiage; to renumber citations and rule provisions based on added and deleted provisions; and to make corrections to units of measure misstated in current rule.

Section 289.251(d)(3) is revised to add the phrase, "to the extent that such person," based upon requirements for compatibility with NRC rule language.

Based upon requirements for compatibility with NRC regulations, §289.251(d)(3)(B)(i) and (ii) revises the exemptions for source material relating to glazed ceramic tableware and glassware, including revisions to add the words "manufactured before August 27, 2013."

In §289.251(d)(3)(E), an exemption to certain counterweights containing depleted uranium which are manufactured in accordance with an NRC license is deleted; in §289.251(d)(3)(E)(i) and (ii), exemptions to counterweights manufactured under a specific license issued by the Atomic Energy Commission are added; and in §289.251(d)(3)(E)(iii), the words "or other" are added and the words "or labeling" are deleted. These changes are made to ensure that, as an agreement state, Texas meets requirements for compatibility with NRC regulations.

In reference to finished optical lenses under exemptions for source materials, the terms "uranium" and "mirror" are added and the words "10% by weight of thorium or uranium or, for lenses manufactured before August 27, 2013," are added in §289.251(d)(3)(G) based upon requirements for compatibility with NRC regulations.

Based upon requirements for compatibility with NRC regulations, new §289.251(d)(5) is added to prohibit unauthorized persons from initially transferring for sale or distribution a product containing source material to persons who are exempt under specified regulations.

Changes are made to §289.251(e)(1)(B) and (C), removing "or the general license provided in §289.252(ee) of this title," from subparagraph (B), and "any agreement state, or any licensing state" from subparagraph (C), based upon requirements for compatibility with NRC regulations.

References to "the agency," "the NRC," or "any agreement state," or the regulations of these agencies, are revised to be consistent with language used throughout the chapter. Revisions are made in §289.251(e)(2)(E); (e)(3)(A)(i)(IV); (e)(3)(C)(iii); (f)(4)(D)(iii)(III); (f)(4)(H)(ii); (f)(4)(H)(iv)(III)(-c-); (f)(4)(H)(iv)(VII) and (IX); and (f)(4)(K)(ii)(VI).

The term "licensing state" has been removed throughout §289.251 because the SSRCR, as written by the CRCPD, no longer uses the terminology. Revisions are reflected in §289.251(e)(1)(B) and (C); (e)(2)(D) and (E); (e)(3)(A)(i)(IV); (e)(3)(C)(iii); (f)(4)(D)(ii) and (iii)(III); (f)(4)(G)(ii)(IV); (f)(4)(G)(iii)(I); (f)(4)(H)(ii); and (f)(4)(H)(iv)(III)(-c-), (VII), and (IX).

The word "commission" is replaced with "NRC" in §289.251(e)(2)(E) to accurately reflect the current standard federal agency nomenclature.

Changes are made to §289.251(e)(3)(A)(i)(IV) and (V), removing "any agreement state, or any licensing state," from (IV) and deleting (V), based upon requirements for compatibility with NRC regulations.

A category for a general license for small quantities of source material is added to §289.251(f)(3)(A) with the revision and deletion of current language and the addition of requirements under the new category of general license, based upon requirements for compatibility with NRC regulations.

Figures: 25 TAC §289.251(f)(4)(D)(iii)(II)(-b-) and §289.251(f)(4)(G)(iii)(II)(-b-) are replaced to remove the term "licensing state" because the SSRCR, as written by the CRCPD, no longer uses the terminology. In addition, the words "or equivalent regulations of the NRC or any agreement state" are added to be consistent with language used throughout the chapter.

In §289.251(f)(4)(F)(i) and (ii), rule references are added to specify, under clause (i), exceptions to the sections of the chapter from which persons who transport and store radioactive material in accordance with a general license under that paragraph are exempt, and, under clause (ii), to specify the provisions in accordance with which the referenced incident notifications are to be filed with the department.

Language is revised in §289.251(f)(4)(H)(iv)(XV) to clarify general license requirements regarding holding devices that are not in use for longer than 24 months.

Section 289.251(f)(4)(H)(iv)(XV)(-b-) adds language providing an alternative to disposal for an agency-approved plan for future use.

In §289.251(f)(4)(K)(ii)(V) and (VI), to improve compatibility with the NRC, the words, "or under equivalent regulations of the NRC, or any agreement state" are added to subclause (V), and "the NRC, or any agreement state" are added to subclause (VI), relating to general license requirements for certain items and self-luminous products containing radium-226.

In addition, §289.251(f)(4)(K)(ii)(VI) replaces "Radiation Safety Licensing Branch" with the word "agency," and adds "agency" to the statement "agency, the NRC, or any agreement state" to be consistent with wording used throughout the chapter.

To maintain appropriate compatibility with NRC regulations, the elements Polonium (84) and Radium (88) are deleted from Figure: 25 TAC §289.251(l)(1), and the elements Beryllium-7, Radon-222, and Strontium-87m are deleted from Figure: 25 TAC §289.251(l)(2). In addition, minor typographical corrections are made to Figure: 25 TAC §289.251(l)(1).

Other changes to §289.251 are made to correct, clarify, or improve terminology, phrasing, grammar and usage, punctuation, and consistency within the section and/or chapter; to include becquerel as well as curie values where both are not included in current rule; to correct or update rule citations, or to renumber citations and rule provisions based on added and deleted provisions; to add, define, or remove acronyms or their definitions; to replace existing numerical references that were spelled out with their corresponding Arabic numerals; and to eliminate unnecessary or redundant verbiage.

In §289.252(d)(8)(A), the words "Division of Licensing, Registration and Standards" are replaced with the word "agency" to be consistent with language used throughout the chapter.

References to "the agency," "the NRC," or "any agreement state," or the regulations of these agencies, are revised to be consistent with language and wording used throughout the chapter. Revisions are made in §289.252(d)(9)(A) and (10); (l)(1) and (3); (l)(4)(B) and (F); (l)(7)(C) and (D); (n)(2); (o)(2); (s)(4)(G); (v)(8)(B)(i); (cc)(3) and (4)(B); and (ee)(1), (1)(E)(i), (2), and (2)(B).

The term "licensing state" has been removed throughout §289.252 because the SSRCR, as written by the CRCPD, no longer uses the terminology. Revisions are reflected in

§289.252(d)(9)(A); (l)(1) and (3); (l)(4)(B) and (F); (l)(7)(C), (C)(iii), and (D); (l)(8); (n)(2); (o)(2); (cc)(2)(D), (3), and (4)(B); and (ee)(1), (ee)(1)(E)(i), (2) and (2)(B).

In §289.252(f)(4)(C)(iii), the words "Nuclear" and "Medical" are transposed to correctly reflect the name of the certification of Nuclear Medical Physics.

The figures in §289.252(l)(1)(C)(iii)(II) and (p)(3)(B) are revised to remove wording relating to "licensing state" because the SSRCR, as written by the CRCPD, no longer uses the terminology. In addition, reference is added to "the agency, the NRC, or any agreement state" for improved compatibility with the NRC.

Recordkeeping language is revised in §289.252(l)(7)(D), (r)(2)(C), (r)(3)(G), (s)(4)(G), (x)(10), (gg)(7), and (ll)(2), due to the addition of a new records retention table in §289.252(mm), and to use consistent language within the chapter and with NRC compatibility requirements, both in the provisions referring to the records retention table in §289.252(mm) and in those imposing recordkeeping requirements without such reference.

To improve requisite compatibility with NRC regulations, throughout §289.252(v), the words "certificate of" are added in front of the term "registration" relating to sealed source or device evaluations.

The term "Radiation Safety Licensing Branch" is replaced with the word "agency" in §289.252(v)(2), (v)(10)(A), and (x)(6) to be consistent with language used throughout the chapter.

New §289.252(x)(11) adds language concerning radioactive waste or sources or devices that are not in use for longer than 24 months to ensure they are being disposed of in a timely fashion. The new language also adds provisions allowing licensees to submit a plan for sources and devices kept in standby for future use or for an alternative timeline for disposal, if the 24-month timeframe cannot be met.

The words "at an entire site" are added to §289.252(y)(4)(C) and the words "in accordance with §289.202(p) of this title" are added to §289.252(y)(15)(B)(ii) to clarify requirements for the expiration and termination of licenses and decommissioning of sites.

New §289.252(cc)(6) adds requirements for the transfer of small quantities of source material for purposes of compatibility with NRC regulations in Title 10, CFR, §40.54 and §40.55.

Current §289.252(ii), relating to "Increased Controls" for "quantities of concern" is replaced with the new "Physical protection requirements of Category 1 and Category 2 quantities of radioactive material" because as an agreement state, Texas must adopt rules that meet the requirements for compatibility with NRC regulations adopted in Title 10, CFR, Part 37. These new provisions include requirements relating to background investigations and access authorization programs; physical protection requirements during use; physical protection in transit; and recordkeeping requirements.

Current Figure: 25 TAC §289.252(jj)(2) is replaced with a new table to place a "T" before the "c" in "Tc-98" in the second to last line of the second group of radionuclides in Figure: 25 TAC §289.252(jj)(2), since it erroneously appears as "c-98" in the figure bearing the same title in current rule.

Current Figure: 25 TAC §289.251(jj)(7) is replaced with a new table to correct the formatting of the alpha and gamma symbols to properly display as such in Figure: 25 TAC §289.251(jj)(7), which they do not in the Figure with the same label published in the current rule. The lettering for the word "emitter" in the third

to last row under the third column bearing the title "Radioactive Material" is also corrected in the new table.

Section 289.252(jj)(9) and Figure: 25 TAC §289.252(jj)(9) are revised to reflect and refer to Category 1 and Category 2 quantities of radioactive material, and to delete language in current §289.252(jj)(9) and the current Figure: 25 TAC §289.252(jj)(9) relating to "quantities of concern." These changes are made based upon requirements for compatibility with NRC regulations.

New §289.252(mm) is added to provide one all-inclusive location that specifies the applicable record/document retention timeframes for records required throughout §289.252. Change is reflected in new Figure: 25 TAC §289.252(mm).

Other changes to §289.252 are made to correct, clarify, or improve terminology, phrasing, grammar and usage, punctuation, and consistency within the section and/or chapter; to add, define, or remove acronyms or their definitions; to replace existing numerical references that were spelled out with their corresponding Arabic numerals; and to include becquerel as well as curie values where both are not included in current rule.

Definitions for "freight forwarder," "registered freight forwarder," "registered shipper," "registered transporter," and "transporter" are added as §289.257(d)(19), (35), (36), (37), and (44) respectively, to clarify the different types of persons or entities that may be transporting radioactive material. Subsequent definitions are renumbered.

The words, "the following limits are not exceeded" is deleted from the definition of "SCO (Surface contaminated object)-II" in §289.257(d)(43)(B), since it is redundant of language contained in each clause that follows.

References to "the agency," or an agency license, are revised to be consistent with language used throughout the chapter. Revisions are made in §289.257(d)(20), (49), and (51).

The new paragraph title "Transporter proof of financial responsibility" is added to §289.257(e)(4) and the current paragraph is revised and divided into four subparagraphs to clarify the requirements for transporters providing proof of financial responsibility.

In §289.257(e)(4)(A), the term "Radiation Safety Licensing Branch" is replaced with the word "agency" to be consistent with language used throughout the chapter. In addition, the words "a registration letter" replace the words "approval of this documentation" to clarify the form in which transporters receive agency approval of their proof of financial responsibility.

Section 289.257(e)(4)(B) is added to specify the expiration date of the transporter registration.

Section 289.257(e)(4)(C) - (D) is revised to include financial responsibility requirements relating to the renewal of the transporter registration, and to add the requirement to provide new proof of financial responsibility if the amount of the liability coverage is reduced or a new policy is purchased.

Language is revised in §289.257(f)(2) regarding exemptions for certain transportation and storage of radioactive material.

The words "transporter and" are added to §289.257(p) to clarify that transporters, in addition to shippers, shall comply with the reports requirement.

References to "telegram" and "mailgram" are deleted in §289.257(p), as the terms are obsolete and language is added to include electronic media transmission as an acceptable mode for meeting the referenced reporting requirements.

In §289.257(q)(3), the words "the shipment" and "licensed" are added and the word "shipments" is deleted, based upon requirements for compatibility with NRC regulations.

Recordkeeping language is revised in §289.257(q)(4)(D) to be consistent with language used throughout the chapter.

The words "registration requirements" are added to the subsection in §289.257(r) and current language is revised as new §289.257(r)(1) to clarify how submission of an emergency plan is approved by the agency.

New §289.257(r)(2) - (4) are added to include specific details relating to the submission, application, expiration, and renewal of an emergency plan registration.

Inadvertent use of a cross-reference to "this subpart," an NRC regulatory, rather than state, rule cross-reference, was deleted and replaced with the specific applicable Chapter 289 rule references in §289.257(s)(1)(C)(ii) to correct the cross-references.

New §289.257(cc)(8) adds a requirement for shippers to submit a list of approved shipping containers intended for use to ship low level radioactive waste for disposal to ensure proper containers are being utilized. Quality assurance documentation and proof of control measures is also required of shippers licensed in Texas who hold a "CoC," a Certificate of Compliance.

Language is deleted to remove reference to "the board" in §289.257(dd)(3) as the term referencing the "Board of Health" is obsolete.

Other changes to §289.257 are made to correct, clarify, or improve terminology, phrasing, grammar and usage, punctuation, and consistency within the section and/or chapter; to add, define, or remove acronyms or abbreviations, or their definitions; to replace existing numerical references that were spelled out with their corresponding Arabic numerals; and to renumber rule provisions based on added and deleted provisions.

COMMENTS

A public hearing was conducted on December 9, 2015. A representative from Gardere was present for the public hearing. The attendee did not have any comments.

The department, on behalf of the commission, has reviewed and prepared responses to the comments received regarding the proposed rules during the comment period, which the commission has reviewed and accepts. The commenters represented Gardere; VEGA Americas, Inc.; and the NRC. The commenters were in favor of the rules, however, some recommendations for change were suggested or are required as discussed in the summary of comments.

A representative from VEGA Americas, Inc., made a recommendation for a typographical change to a posted information memorandum concerning rule revisions, comment deadline, and public hearing date which accompanied the proposed rule text for Section 289.251 on the radiation program website. The department corrected the information memorandum to reflect that "...devices that are not in use for longer than 24 months." The information memorandum was withdrawn from the website after the comment period ended.

Comment: A representative from Gardere expressed concern regarding the implementation timeframe for these rules.

Response: The commission acknowledges the concern and provides the following information. The intention is to have the rules in place and effective no later than March 19, 2016. If, for

whatever reason, it appears that the rules will not be in place by that date, licensing conditions will be applied which will be in effect by that date. Additional implementation information was posted on the radiation website on January 14, 2016, at <http://www.dshs.state.tx.us/radiation/proposed.shtm>. No change was made to the rules as a result of the comment.

Comment: The NRC stated that the Mail Stop for NRC's Criminal History Program in §289.252(ii)(5)(C)(i) needs to be updated to read "TWB-05 B32M" as the mail stop has changed.

Response: The commission agrees and the correction has been made.

Comment: The NRC stated that the word "federal" needs to be removed before the words "agency/employer" in §289.252(ii)(6)(A)(xii) and §289.252(ii)(6)(B) to meet the Compatibility Category B designation assigned to 10 CFR 37.29(a)(12) and 37.29(b).

Response: The commission agrees and the word "federal" has been removed in the rule text in §289.252(ii)(6)(A)(xii) and (ii)(6)(B). The figure in §289.252(mm) has also been revised in the second column titled Name of Records. In the rule cross reference for §289.252(ii)(6)(A)(xii) and (ii)(6)(B), the word "federal" was removed to reflect the same wording as in the rule text.

Comment: Regarding §289.252(ii)(9)(A)(ii), the NRC stated that the first sentence should read "An applicant for a new license and each licensee that would become newly subject to..." to meet the Compatibility Category B designation assigned to 10 CFR 37.41(a).

Response: The commission agrees and the word "newly" has been added.

Comment: Regarding §289.252(ii)(21)(A) - (D), the NRC stated that the NRC addresses for advance notification need to be replaced with the appropriate state agency information to meet the Compatibility Category B designation assigned to 10 CFR 37.77(a) - (d).

Response: The commission agrees. References to the NRC have been removed and replaced with references to the Texas Department of Public Safety, Office of Homeland Security, as the appropriate agency to be notified in advance of shipments of Category 1 and Category 2 quantities of radioactive material in Texas.

DEPARTMENT COMMENTS

The department staff, on behalf of the commission, provided one comment and the commission has reviewed and agrees to the following change.

The word "agency" was added in §289.252(ii)(21)(F) to correctly include licensees of the agency.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the rules, as adopted, have been reviewed by legal counsel and found to be a valid exercise of the agencies' legal authority.

SUBCHAPTER D. GENERAL

25 TAC §§289.201, §289.202

STATUTORY AUTHORITY

The amendments are adopted under Health and Safety Code, Chapter 401, which provides for the department's radiation control rules and regulatory program to be compatible with federal standards and regulation; §401.065, which permits Texas to enter an agreement with the federal government to perform functions relating to radiation control, in cooperation with the federal government, and Texas' status thereto as an Agreement State, under which it is required to comply with NRC requirements for compatibility with its regulations; §401.051, which provides the required authority to adopt rules and guidelines relating to the control of sources of radiation; §401.052, which provides authority for rules that provide for transportation and routing of radioactive material and waste in Texas; §401.103, which provides authority for licensing and registration for transportation of sources of radiation; §401.104 which provides for rulemaking authority for general or specific licensing of radioactive material and devices or equipment using radioactive material; §401.224, which provides rulemaking authority relating to the packaging of radioactive waste; and Government Code, §531.0055; and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. The review of the rules implements Government Code, §2001.039.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on February 10, 2016.

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Lisa Hernandez
General Counsel

Department of State Health Services

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For further information, please call: (512) 776-6972



SUBCHAPTER F. LICENSE REGULATIONS

25 TAC §§289.251, 289.252, 289.257

STATUTORY AUTHORITY

The amendments are adopted under Health and Safety Code, Chapter 401, which provides for the department's radiation control rules and regulatory program to be compatible with federal standards and regulation; §401.065, which permits Texas to enter an agreement with the federal government to perform functions relating to radiation control, in cooperation with the federal government, and Texas' status thereto as an Agreement State, under which it is required to comply with NRC requirements for compatibility with its regulations; §401.051, which provides the required authority to adopt rules and guidelines relating to the control of sources of radiation; §401.052, which provides authority for rules that provide for transportation and routing of radioactive material and waste in Texas; §401.103, which provides authority for licensing and registration for transportation of sources of radiation; §401.104 which provides for rulemaking authority for general or specific licensing of radioactive material and devices or equipment using radioactive material; §401.224, which pro-

vides rulemaking authority relating to the packaging of radioactive waste; and Government Code, §531.0055; and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. The review of the rules implements Government Code, §2001.039.

§289.252. *Licensing of Radioactive Material.*

(a) Purpose. The intent of this section is as follows.

(1) This section provides for the specific licensing of radioactive material.

(2) Unless otherwise exempted, no person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized by the following:

(A) a specific license issued in accordance with this section and/or any of the following sections:

(i) §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography);

(ii) §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material);

(iii) §289.258 of this title (relating to Licensing and Radiation Safety Requirements for Irradiators); and/or

(iv) §289.259 of this title (relating to Licensing of Naturally Occurring Radioactive Material (NORM)); or

(B) a general license or general license acknowledgment issued in accordance with §289.251 of this title (relating to Exemptions, General Licenses, and General License Acknowledgments).

(3) A person who receives, possesses, uses, transfers, owns, or acquires radioactive materials prior to receiving a license is subject to the requirements of this chapter.

(b) Scope. In addition to the requirements of this section, the following additional requirements are applicable.

(1) All licensees, unless otherwise specified, are subject to the requirements in the following sections:

(A) §289.201 of this title (relating to General Provisions for Radioactive Material);

(B) §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials);

(C) §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections);

(D) §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);

(E) §289.205 of this title (relating to Hearing and Enforcement Procedures); and

(F) §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(2) Licensees engaged in well logging service operations and tracer studies are subject to the requirements of §289.253 of this title (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies).

(3) Licensees engaged in industrial radiographic operations are subject to the requirements of §289.255 of this title.

(4) Licensees using radioactive material for medical or veterinary use are subject to the requirements of §289.256 of this title.

(5) Licensees using sealed sources in irradiators are subject to the requirements of §289.258 of this title.

(6) Licensees possessing or using naturally occurring radioactive material are subject to the requirements of §289.259 of this title.

(c) Types of licenses. Licenses for radioactive materials are of two types: general and specific.

(1) General licenses provided in §289.251 and §289.259 of this title are effective without the filing of applications with the agency or the issuance of licensing documents to the particular persons, although the filing of an application for acknowledgement with the agency may be required for a particular general license. The general licensee is subject to any other applicable portions of this chapter and any limitations of the general license.

(2) Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable portions of this chapter as well as any limitations specified in the licensing document.

(d) Filing application for specific licenses. The agency may, at any time after the filing of the original application, require further statements in order to enable the agency to determine whether the application should be denied or the license should be issued.

(1) Applications for specific licenses shall be filed in a manner prescribed by the agency.

(2) Each application shall be signed by the chief executive officer or other individual delegated the authority to manage, direct, or administer the licensee's activities.

(3) An application for a license may include a request for a license authorizing one or more activities. The agency may require the issuance of separate specific licenses for those activities.

(4) Each application for a specific license, other than a license exempted from §289.204 of this title, shall be accompanied by the fee prescribed in §289.204 of this title.

(5) Each application shall be accompanied by a completed RC Form 252-1 (Business Information Form).

(6) Each applicant shall demonstrate to the agency that the applicant is financially qualified to conduct the activity requested for licensure, including any required decontamination, decommissioning, reclamation, and disposal before the agency issues a license. Each licensee shall demonstrate to the agency that it remains financially qualified to conduct the licensed activity before a license is renewed. Methods for demonstrating financial qualifications are specified in subsection (jj)(8) of this section. The requirement for demonstration of financial qualification is separate from the requirement specified in subsection (gg) of this section for certain applicants or licensees to provide financial assurance.

(7) If facility drawings submitted in conjunction with the application for a license are prepared by a professional engineer or engineering firm, those drawings shall be final and shall be signed, sealed and dated in accordance with the requirements of the Texas Board of Professional Engineers, Title 22, Texas Administrative Code (TAC), Chapter 131.

(8) Applications for licenses shall be processed in accordance with the following time periods.

(A) The first period is the time from receipt of an application by the agency to the date of issuance or denial of the license or a written notice outlining why the application is incomplete or unacceptable. This time period is 60 days.

(B) The second period is the time from receipt of the last item necessary to complete the application to the date of issuance or denial of the license. This time period is 30 days.

(C) These time periods are exclusive of any time period incident to hearings and post-hearing activities required by the Government Code, Chapter 2001.

(9) Except as provided in this paragraph, an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall:

(A) identify the source or device by manufacturer and model number as registered in accordance with subsection (v) of this section or with equivalent regulations of the United States Nuclear Regulatory Commission (NRC) or any agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material registered in accordance with subsection (v) of this section; or

(B) contain the information specified in subsection (v)(3) - (4) of this section.

(10) For sources or devices manufactured before October 23, 2012, that are not registered in accordance with subsection (v) of this section or with equivalent regulations of the NRC or any agreement state, and for which the applicant is unable to provide all categories of information specified in subsection (v)(3) - (4) of this section, the application shall include:

(A) all available information identified in subsection (v)(3) - (4) of this section concerning the source, and, if applicable, the device; and

(B) sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information shall include:

- (i) a description of the source or device;
- (ii) a description of radiation safety features;
- (iii) the intended use and associated operating experience; and
- (iv) the results of a recent leak test.

(11) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with subsection (v)(8)(A) of this section, the applicant shall supply only the manufacturer, model number, and radionuclide and quantity.

(12) If it is not feasible to identify each sealed source and device individually, the applicant shall propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

(13) Notwithstanding the provisions of §289.204(d)(1) of this title, reimbursement of application fees may be granted in the following manner.

(A) In the event the application is not processed in the time periods as stated in paragraph (8) of this subsection, the applicant has the right to request of the director of the Radiation Control Pro-

gram full reimbursement of all application fees paid in that particular application process. If the director does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request will be denied.

(B) Good cause for exceeding the period established is considered to exist if:

(i) the number of applications for licenses to be processed exceeds by 15% or more the number processed in the same calendar quarter the preceding year;

(ii) another public or private entity utilized in the application process caused the delay; or

(iii) other conditions existed giving good cause for exceeding the established periods.

(C) If the request for full reimbursement authorized by subparagraph (A) of this paragraph is denied, the applicant may then request a hearing by appeal to the Commissioner of Health for a resolution of the dispute. The appeal will be processed in accordance with Title 1, TAC, Chapter 155, and the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title.

(14) Applications for licenses may be denied for the following reasons:

(A) any material false statement in the application or any statement of fact required under provisions of the Texas Radiation Control Act (Act);

(B) conditions revealed by the application or statement of fact or any report, record, or inspection, or other means that would warrant the agency to refuse to grant a license on an application; or

(C) failure to clearly demonstrate how the requirements in this chapter have been addressed.

(15) Action on a specific license application will be considered abandoned if the applicant does not respond within 30 days from the date of a request for any information by the agency. Abandonment of such actions does not provide an opportunity for a hearing; however, the applicant retains the right to resubmit the application in accordance with paragraphs (1) - (7) of this subsection.

(e) General requirements for the issuance of specific licenses. A license application will be approved if the agency determines that:

(1) the applicant and all personnel who will be handling the radioactive material are qualified by reason of training and experience to use the material in question for the purpose requested in accordance with this chapter in such a manner as to minimize danger to occupational and public health and safety and the environment;

(2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to occupational and public health and safety and the environment;

(3) the issuance of the license will not be inimical to the health and safety of the public;

(4) the applicant satisfied any applicable special requirement in this section and other sections as specified in subsection (a)(2)(A) of this section;

(5) the radiation safety information submitted for requested sealed source(s) or device(s) containing radioactive material is in accordance with subsection (v) of this section;

(6) qualifications of the designated radiation safety officer (RSO) as specified in subsection (f) of this section are adequate for the purpose requested in the application;

(7) the applicant submitted adequate operating, safety, and emergency procedures;

(8) the applicant's permanent facility is located in Texas (if the applicant's permanent facility is not located in Texas, reciprocal recognition shall be sought as required by subsection (ee) of this section);

(9) the owner of the property is aware that radioactive material is stored and/or used on the property, if the proposed facility is not owned by the applicant. The applicant shall provide a written statement from the owner, or from the owner's agent, indicating such. This paragraph does not apply to property owned or held by a government entity or to property on which radioactive material is used under an authorization for temporary job site use;

(10) there is no reason to deny the license as specified in subsections (d)(14) or (x)(9) of this section; and

(11) the applicant is listed on the Secretary of State's website as authorized to conduct business in the state, unless the applicant is exempt. All applicants using an assumed name in their application shall file an assumed name certificate with the Secretary of State and/or the office of the county clerk as required under the Business and Commerce Code, Chapter 71.

(f) Radiation safety officer.

(1) An RSO shall be designated for every license issued by the agency. A single individual may be designated as RSO for more than one license if authorized by the agency.

(2) The RSO's documented qualifications shall include as a minimum:

(A) possession of a high school diploma or a certificate of high school equivalency based on the GED test;

(B) completion of the training and testing requirements specified in this chapter for the activities for which the license application is submitted; and

(C) training and experience necessary to supervise the radiation safety aspects of the licensed activity.

(3) The specific duties of the RSO include, but are not limited to, the following:

(A) to establish and oversee operating, safety, emergency, and as low as reasonably achievable (ALARA) procedures, and to review them at least annually to ensure that the procedures are current and conform with this chapter;

(B) to oversee and approve all phases of the training program for operations and/or personnel so that appropriate and effective radiation protection practices are taught;

(C) to ensure that required radiation surveys and leak tests are performed and documented in accordance with this chapter, including any corrective measures when levels of radiation exceed established limits;

(D) to ensure that individual monitoring devices are used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made in accordance with §289.203 of this title;

(E) to investigate and cause a report to be submitted to the agency for each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter and each theft or loss of source(s) of radiation, to determine the cause(s), and to take steps to prevent a recurrence;

(F) to investigate and cause a report to be submitted to the agency for each known or suspected case of release of radioactive material to the environment in excess of limits established by this chapter;

(G) to have a thorough knowledge of management policies and administrative procedures of the licensee;

(H) to assume control and have the authority to institute corrective actions, including shutdown of operations when necessary in emergency situations or unsafe conditions;

(I) to ensure that records are maintained as required by this chapter;

(J) to ensure the proper storing, labeling, transport, use and disposal of sources of radiation, storage, and/or transport containers;

(K) to ensure that inventories are performed in accordance with the activities for which the license application is submitted;

(L) to perform a physical inventory of the radioactive sealed sources authorized for use on the license every 6 months and make, maintain, and retain records of the inventory of the radioactive sealed sources authorized for use on the license every 6 months, to include, but not be limited to the following:

(i) isotope(s);

(ii) quantity(ies);

(iii) activity(ies);

(iv) date inventory is performed;

(v) location;

(vi) unique identifying number or serial number; and

(vii) signature of person performing the inventory;

(M) to ensure that personnel are complying with this chapter, the conditions of the license, and the operating, safety, and emergency procedures of the licensee;

(N) to serve as the primary contact with the agency; and

(O) to have knowledge of and ensure compliance with federal and state security measures for radioactive material.

(4) Requirements for RSOs for specific licenses for broad scope authorization for research and development. In addition to the requirements in paragraphs (1) and (3) of this subsection, the RSO's qualifications for specific licenses for broad scope authorization for research and development shall include evidence of the following:

(A) a bachelor's degree in health physics, radiological health, physical science or a biological science with a physical science minor and 4 years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed;

(B) a master's degree in health physics or radiological health and 3 years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed;

(C) 2 years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed and one of the following:

(i) doctorate degree in health physics or radiological health;

(ii) comprehensive certification by the American Board of Health Physics;

(iii) certification by the American Board of Radiology in Nuclear Medical Physics;

(iv) certification by the American Board of Science in Nuclear Medicine in Radiation Protection; or

(v) certification by the American Board of Medical Physics in Medical Health Physics; or

(D) equivalent qualifications as approved by the agency.

(5) The qualifications in paragraph (4)(A) - (D) do not apply to individuals who have been adequately trained and designated as RSOs on licenses issued prior to October 1, 2000.

(g) Duties and responsibilities of the Radiation Safety Committee (RSC). The duties and responsibilities of the RSC include but are not limited to the following:

(1) meeting as often as necessary to conduct business but no less than 3 times a year;

(2) reviewing summaries of the following information presented by the RSO:

(A) over-exposures;

(B) significant incidents, including spills, contamination, or medical events; and

(C) items of non-compliance following an inspection;

(3) reviewing the program for maintaining doses ALARA, and providing any necessary recommendations to ensure doses are ALARA;

(4) reviewing the overall compliance status for authorized users;

(5) sharing responsibility with the RSO to conduct periodic audits of the radiation safety program;

(6) reviewing the audit of the radiation safety program and acting upon the findings;

(7) developing criteria to evaluate training and experience of new authorized user applicants;

(8) evaluating and approving authorized user applicants who request authorization to use radioactive material at the facility;

(9) evaluating new uses of radioactive material;

(10) reviewing and approving permitted program and procedural changes prior to implementation; and

(11) having knowledge of and ensuring compliance with federal and state security measures for radioactive material.

(h) Specific licenses for broad scope authorization for multiple quantities or types of radioactive material for use in research and development.

(1) In addition to the requirements in subsection (e) of this section, a specific license for multiple quantities or types of radioactive material for use in research and development, not to include the internal or external administration of radiation or radioactive material to humans, will be issued if the agency approves the following documentation submitted by the applicant:

(A) that staff has substantial experience in the use of a variety of radioisotopes for a variety of research and development uses;

(B) of a full-time RSO meeting the requirements of subsection (f)(4) of this section;

(C) establishment of an RSC, including names and qualifications, with duties and responsibilities in accordance with subsection (g) of this section. The RSC shall be composed of an RSO, a representative of executive management, and 1 or more persons trained or experienced in the safe use of radioactive materials.

(2) Unless specifically authorized, persons licensed according to paragraph (1) of this subsection shall not conduct tracer studies involving direct release of radioactive material to the environment.

(3) Unless specifically authorized, in accordance with a separate license, persons licensed according to paragraph (1) of this subsection shall not:

(A) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (Ci) (3700 terabecquerels) or more of radioactive material in sealed sources used for irradiation of materials;

(B) conduct activities for which a specific license issued by the agency in accordance with subsections (i) - (u) of this section and §289.255, §289.256, and §289.259 of this title as required;

(C) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being; or

(D) commercially distribute radioactive material.

(i) Specific licenses for introduction of radioactive material into products in exempt concentrations.

(1) In addition to the requirements in subsection (e) of this section, a specific license authorizing the introduction of radioactive material into a product or material in the possession of the licensee or another to be transferred to persons exempt from this chapter in accordance with §289.251(e)(1)(A) of this title will be issued if the agency approves the following information submitted by the applicant:

(A) a description of the product or material into which the radioactive material will be introduced;

(B) intended use of the radioactive material and the product or material into which it is introduced;

(C) method of introduction;

(D) initial concentration of the radioactive material in the product or material;

(E) control methods to assure that no more than the specified concentration is introduced into the product or material;

(F) estimated time interval between introduction and transfer of the product or material;

(G) estimated concentration of the radioactive material in the product or material at the time of transfer; and

(H) procedures for disposition of unwanted or unused radioactive material.

(2) The applicant shall provide reasonable assurance that:

(A) the concentrations of radioactive material at the time of transfer will not exceed the concentrations in §289.251(m)(1) of this title;

(B) reconcentration of the radioactive material in concentrations exceeding those in §289.251(m)(1) of this title will not occur;

(C) the use of lower concentrations is not feasible; and

(D) the product or material is not to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human.

(3) Each person licensed in accordance with this subsection shall file an annual report with the agency and shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period. The report shall cover the year ending June 30, shall be filed within 30 days thereafter, and shall include the following:

(A) name and address of the person who owned or possessed the product or material when the radioactive material was introduced;

(B) the type and quantity of radionuclide introduced into each such product or material; and

(C) the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

(4) If no transfers of radioactive material have been made in accordance with this subsection during the reporting period, the report shall so indicate.

(5) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt in accordance with §289.251 of this title except as specified with a license issued by the NRC.

(j) Specific licenses for commercial distribution of radioactive material in exempt quantities.

(1) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material, byproduct material, or naturally occurring and accelerator-produced radioactive material (NARM) whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission (NRC), Washington, DC 20555 in accordance with Title 10, Code of Federal Regulations (CFR), §32.18.

(2) Licenses issued in accordance with this subsection do not authorize the following:

(A) combining of exempt quantities of radioactive material in a single device;

(B) any program advising persons to combine exempt quantity sources and providing devices for them to do so; and

(C) the possession and use of combined exempt sources, in a single unregistered device, by persons exempt from licensing in accordance with §289.251(e)(2) of this title.

(k) Specific licenses for incorporation of byproduct material or NARM into gas and aerosol detectors. A specific license authorizing the incorporation of byproduct material or NARM into gas and aerosol detectors to be distributed to persons exempt from this chapter shall be issued only by the NRC in accordance with Title 10, CFR, §32.26.

(l) Specific licenses for the manufacture and commercial distribution of devices to persons generally licensed in accordance with §289.251(f)(4)(H) of this title.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture or commercially distribute devices containing radioactive material to persons generally licensed in

accordance with §289.251(f)(4)(H) of this title or equivalent requirements of the NRC or any agreement state will be issued if the agency approves the following information submitted by the applicant:

(A) the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(i) the device can be safely operated by persons not having training in radiological protection;

(ii) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one year a dose in excess of 10% of the limits specified in §289.202(f) of this title; and

(iii) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

(I) 15 rems to the whole body; head and trunk; active blood-forming organs; gonads; or lens of eye;

(II) 200 rems to the hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter (cm²); or

(III) 50 rems to other organs;

(B) procedures for disposition of unused or unwanted radioactive material;

(C) each device bears a durable, legible, clearly visible label or labels approved by the agency that contain the following in a clearly identified and separate statement:

(i) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(ii) the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(iii) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(I) For radioactive materials other than NARM, the following statement is appropriate:

Figure: 25 TAC §289.252(l)(1)(C)(iii)(I) (No change.)

(II) For NARM, the following statement is appropriate:

Figure: 25 TAC §289.252(l)(1)(C)(iii)(II)

(III) The model and serial number and name of manufacturer or distributor may be omitted from this label provided they are elsewhere stated in labeling affixed to the device.

(D) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial numbers, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in §289.202(z) of this title, and the name of the manufacturer or initial distributor.

(E) Each device meeting the criteria of §289.251(g)(1) of this title, bears a permanent (for example, embossed, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in §289.202(z) of this title.

(F) The device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material, or for both, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the device or similar devices and by design features that have a significant bearing on the probability or consequences of radioactive material leakage from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for radioactive material leakage, the agency will consider information that includes, but is not limited to the following:

- (A) primary containment (sealed source capsule);
- (B) protection of primary containment;
- (C) method of sealing containment;
- (D) containment construction materials;
- (E) form of contained radioactive material;
- (F) maximum temperature withstood during prototype tests;
- (G) maximum pressure withstood during prototype tests;
- (H) maximum quantity of contained radioactive material;
- (I) radiotoxicity of contained radioactive material; and
- (J) operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee in accordance with §289.251(f)(4)(H) of this title or in accordance with equivalent regulations of the NRC or any agreement state, be authorized to mount the device, collect the sample to be analyzed by a specific licensee for radioactive material leakage, perform maintenance of the device consisting of replacement of labels, rust and corrosion prevention, and for fixed gauges, repair and maintenance of sealed source holder mounting brackets, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated annual doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices in accordance with the general license, is unlikely to cause that individual to receive an annual dose in excess of 10% of the limits specified in §289.202(f) of this title.

(4) Before the device may be transferred, each person licensed in accordance with this subsection to commercially distribute devices to generally licensed persons shall furnish:

(A) a copy of the general license in §289.251(f)(4)(H) of this title to each person to whom the licensee directly commercially

distributes radioactive material in a device for use in accordance with the general license in §289.251(f)(4)(H) of this title;

(B) a copy of the general license in the NRC's or any agreement state's regulation equivalent to §289.251(f)(4)(H) of this title, or alternatively, a copy of the general license in §289.251(f)(4)(H) of this title to each person to whom the licensee directly commercially distributes radioactive material in a device for use in accordance with the general license of the NRC or any agreement state. If certain requirements of the regulations do not apply to the particular device, those requirements may be omitted. If a copy of the general license in §289.251(f)(4)(H) of this title is furnished to such a person, it shall be accompanied by an explanation that the use of the device is regulated by the NRC or any agreement state in accordance with requirements substantially the same as those in §289.251(f)(4)(H) of this title;

(C) a copy of §289.251(g) of this title;

(D) a list of the services that can only be performed by a specific licensee;

(E) information on acceptable disposal options including estimated costs of disposal;

(F) the name or position, address, and phone number of a contact person at the agency, the NRC, or any agreement state, from which additional information may be obtained; and

(G) an indication that it is the NRC's policy to issue high civil penalties for improper disposal if the device is commercially distributed to a general licensee of the NRC.

(5) An alternative approach to informing customers may be submitted by the licensee for approval by the agency.

(6) In the case of a transfer through an intermediate person, each licensee who commercially distributes radioactive material in a device for use in accordance with the general license in §289.251(f)(4)(H) of this title, shall furnish the information in paragraph (4) of this subsection to the intended user prior to the initial transfer to the intermediate person.

(7) Each person licensed in accordance with this subsection to commercially distribute devices to generally licensed persons shall:

(A) report to the agency all commercial distributions of devices to persons for use in accordance with the general license in §289.251(f)(4)(H) of this title and all receipts of devices from general licensees licensed in accordance with §289.251(f)(4)(H) of this title.

(i) The report shall:

(I) cover each calendar quarter;

(II) be filed within 30 days thereafter;

(III) be submitted on a form prescribed by the agency or in a clear and legible report containing all of the data required by the form;

(IV) clearly indicate the period covered by the report;

(V) clearly identify the specific licensee submitting the report and include the license number of the specific licensee;

(VI) identify each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

(VII) identify an individual by name, title, and phone number who has knowledge of and authority to take required

actions to ensure compliance with the appropriate regulations and requirements;

(VIII) identify the type, model and serial number of device, and serial number of sealed source commercially distributed;

(IX) identify the quantity and type of radioactive material contained in the device; and

(X) include the date of transfer.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall also include the information in accordance with paragraph (7)(A)(i) of this subsection for both the intended user and each intermediate person and clearly designate the intermediate person(s).

(iii) If no commercial distributions have been made to persons generally licensed in accordance with §289.251(f)(4)(H) of this title during the reporting period, the report shall so indicate.

(iv) For devices received from a general licensee, the report shall include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(B) report the following to the NRC to include covering each calendar quarter to be filed within 30 days thereafter, clearly indicating the period covered by the report, the identity of the specific licensee submitting the report, and the license number of the specific licensee:

(i) all commercial distributions of such devices to persons for use in accordance with the NRC general license in Title 10, CFR, §31.5 and all receipts of devices from general licensees in areas under NRC jurisdiction including the following:

(I) identity of each general licensee by name and address;

(II) the type, model and serial number of device, and serial number of sealed source commercially distributed;

(III) the quantity and type of radioactive material contained in the device;

(IV) the date of transfer; or

(ii) if the licensee makes changes to a device possessed in accordance with the general license in §289.251(f)(4)(H) of this title, such that the label must be changed to update required information, the report shall identify the licensee, the device, and the changes to information on the device label;

(iii) in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor;

(iv) if no commercial distributions have been made to the NRC licensees during the reporting period; the report shall so indicate;

(C) report to the agency or any agreement state all transfers of devices manufactured and commercially distributed in accordance with this subsection for use in accordance with a general license in that state's requirements equivalent to §289.251(f)(4)(H) of this title and all receipts of devices from general licensees.

(i) The report shall:

(I) be submitted within 30 days after the end of each calendar quarter in which such a device is commercially distributed to the generally licensed person;

(II) clearly indicate the period covered by the report;

(III) clearly identify the specific licensee submitting the report and include the license number of the specific licensee;

(IV) identify each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use an alternate address for the licensee shall be submitted along with the information on the actual location of use;

(V) identify an individual by name, position, and phone number who has knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(VI) include the type, model and serial number of the device, and serial number of sealed source commercially distributed;

(VII) include the quantity and type of radioactive material contained in the device; and

(VIII) include the date of receipt.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall also include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(iii) If no commercial distributions have been made to persons in the agreement state during the reporting period, the report shall so indicate.

(iv) For devices received from a general licensee, the report shall include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor; and

(D) make, maintain, and retain records required by this paragraph for inspection by the agency in accordance with subsection (mm) of this section, including the name, address, and the point of contact for each general licensee to whom the licensee directly or through an intermediate person commercially distributes radioactive material in devices for use in accordance with the general license provided in §289.251(f)(4)(H) of this title, or equivalent requirements of the NRC or any agreement state.

(i) The records shall include the following:

(I) the date of each commercial distribution;

(II) the isotope and the quantity of radioactivity in each device commercially distributed;

(III) the identity of any intermediate person; and

(IV) compliance with the reporting requirements of this subsection.

(ii) If no commercial distributions have been made to persons generally licensed in accordance with §289.251(f)(4)(H) of this title during the reporting period, the records shall so indicate.

(8) If a notification of bankruptcy has been made in accordance with subsection (x)(6) of this section or the license is to be ter-

minated, each person licensed in accordance with this subsection shall provide, upon request to the NRC and to any appropriate agreement state, records of final disposition required in accordance with subsection (y)(16)(A) of this section.

(9) Each device that is transferred after February 19, 2002, shall meet the labeling requirements in accordance with paragraph (1)(C) - (E) of this subsection.

(m) Specific licenses for the manufacture, assembly, repair, or initial transfer of luminous safety devices containing tritium or promethium-147 for use in aircraft for distribution to persons generally licensed in accordance with §289.251(f)(4)(B) of this title. In addition to the requirements in subsection (e) of this section, a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed in accordance with §289.251(f)(4)(B) of this title, will be issued if the agency approves the information submitted by the applicant. The information shall satisfy the requirements of Title 10, CFR, §§32.53, 32.54, 32.55, and 32.56, or their equivalent.

(n) Specific licenses for the manufacture or initial transfer of calibration sources containing americium-241 or radium-226 for commercial distribution to persons generally licensed in accordance with §289.251(f)(4)(D) of this title.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture or initially transfer calibration sources containing americium-241, or radium-226 to persons generally licensed in accordance with §289.251(f)(4)(D) of this title will be issued if the agency approves the information submitted by the applicant. The information shall satisfy the requirements of Title 10, CFR, §§32.57, 32.58, 32.59, and §70.39 or their equivalent.

(2) Each person licensed in accordance with this subsection shall perform a dry wipe test on each source containing more than 0.1 μCi (3.7 kilobecquerels (kBq)) of americium-241 or radium-226 before transferring the source to a general licensee in accordance with §289.251(f)(4)(D) of this title or equivalent regulations of the NRC or any agreement state. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 μCi (0.185 kBq) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.005 μCi (0.185 kBq) of americium-241 or radium-226 by methods described in this paragraph, the source shall be rejected and shall not be transferred to a general licensee in accordance with §289.251(f)(4)(D) of this title or equivalent regulations of the NRC or any agreement state.

(o) Specific licenses for the manufacture and commercial distribution of sealed sources or devices containing radioactive material for medical use. In addition to the requirements in subsection (e) of this section, a specific license to manufacture and commercially distribute sealed sources and devices containing radioactive material to persons licensed in accordance with §289.256 of this title for use as a calibration, transmission, or reference source or for use of sealed sources listed in §289.256(q), (rr), (bbb), and (ddd) of this title will be issued if the agency approves the following information submitted by the applicant:

(1) an evaluation of the radiation safety of each type of sealed source or device including the following:

(A) the radioactive material contained, its chemical and physical form, and amount;

(B) details of design and construction of the sealed source or device;

(C) procedures for, and results of, prototype tests to demonstrate that the sealed source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(D) for devices containing radioactive material, the radiation profile of a prototype device;

(E) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(F) procedures and standards for calibrating sealed sources and devices;

(G) instructions for handling and storing the sealed source or device from the radiation safety standpoint. These instructions are to be included on a durable label attached to the sealed source or device or attached to a permanent storage container for the sealed source or device, provided that instructions that are too lengthy for the label may be summarized on the label and printed in detail on a brochure that is referenced on the label; and

(H) a legend and methods for labeling sources and devices as to their radioactive content;

(2) documentation that the label affixed to the sealed source or device, or to the permanent storage container for the sealed source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the name of the sealed source or device is licensed by the agency for commercial distribution to persons licensed for use of sealed sources in the healing arts or by equivalent licenses of the NRC or any agreement state;

(3) documentation that in the event the applicant desires that the sealed source or device be required to be tested for radioactive material leakage at intervals longer than 6 months, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the sealed source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of radioactive material leakage from the sealed source;

(4) documentation that in determining the acceptable interval for testing radioactive material leakage, information will be considered that includes, but is not limited to the following:

(A) primary containment (sealed source capsule);

(B) protection of primary containment;

(C) method of sealing containment;

(D) containment construction materials;

(E) form of contained radioactive material;

(F) maximum temperature withstood during prototype tests;

(G) maximum pressure withstood during prototype tests;

(H) maximum quantity of contained radioactive material;

(I) radiotoxicity of contained radioactive material; and

(J) operating experience with identical sealed sources or devices or similarly designed and constructed sealed sources or devices; and

(5) the source or device has been registered in the Sealed Source and Device Registry.

(p) Specific licenses for the manufacture and commercial distribution of radioactive material for certain *in vitro* clinical or laboratory testing in accordance with the general license. In addition to the requirements in subsection (e) of this section, a specific license to manufacture or commercially distribute radioactive material for use in accordance with the general license in §289.251(f)(4)(G) of this title will be issued if the agency approves the following information submitted by the applicant:

(1) documentation that the radioactive material will be prepared for distribution in prepackaged units of:

(A) iodine-125 in units not exceeding 10 μCi (0.37 megabecquerel (MBq)) each;

(B) iodine-131 in units not exceeding 10 μCi (0.37 MBq) each;

(C) carbon-14 in units not exceeding 10 μCi (0.37 MBq) each;

(D) hydrogen-3 (tritium) in units not exceeding 50 μCi (1.85 MBq) each;

(E) iron-59 in units not exceeding 20 μCi (0.74 MBq) each;

(F) cobalt-57 in units not exceeding 10 μCi (0.37 MBq) each;

(G) selenium-75 in units not exceeding 10 μCi (0.37 MBq) each; or

(H) mock iodine-125 in units not exceeding 0.05 μCi (1.85 kBq) of iodine-129 and 0.005 μCi (0.185 kBq) of americium-241 each;

(2) evidence that each prepackaged unit will bear a durable, clearly visible label:

(A) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 μCi (0.37 MBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 μCi (1.85 MBq) of hydrogen-3 (tritium); 20 μCi (0.74 MBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 μCi (1.85 kBq) of iodine-129 and 0.005 μCi (0.185 kBq) of americium-241; and

(B) displaying the radiation caution symbol in accordance with §289.202(z) of this title and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals";

(3) that one of the following statements, as appropriate, or a substantially similar statement appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

(A) option 1:

Figure: 25 TAC §289.252(p)(3)(A) (No change.)

(B) option 2:

Figure: 25 TAC §289.252(p)(3)(B)

(4) that the label affixed to the unit, or the leaflet or brochure that accompanies the package, contains adequate information as to the precautions to be observed in handling and storing the radioactive material. In the case of a mock iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements of §289.202(ff) of this title.

(q) Specific licenses for the manufacture and commercial distribution of ice detection devices. In addition to the requirements of subsection (e) of this section, a specific license to manufacture and commercially distribute ice detection devices to persons generally licensed in accordance with §289.251(f)(4)(E) of this title will be issued if the agency approves the information submitted by the applicant. This information shall satisfy the requirements of Title 10, CFR, §§32.61 and 32.62.

(r) Specific licenses for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive materials for medical use.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture, prepare, or transfer for commercial distribution, radioactive drugs containing radioactive material for use by persons authorized in accordance with §289.256 of this title will be issued if the agency approves the following information submitted by the applicant:

(A) evidence that the applicant is at least one of the following:

(i) registered with the United States Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug in accordance with Title 21, CFR, §207.20(a);

(ii) registered or licensed with a state agency as a drug manufacturer;

(iii) licensed as a pharmacy by the Texas State Board of Pharmacy;

(iv) operating as a nuclear pharmacy within a federal medical institution; or

(v) a positron emission tomography (PET) drug production facility registered with a state agency;

(B) radionuclide data relating to the following:

(i) chemical and physical form;

(ii) maximum activity per vial, syringe, generator, or other container of the radioactive drug; and

(iii) shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees;

(C) labeling requirements including the following:

(i) that each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution shall include the following:

(I) the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL;"

(II) the name of the radioactive drug or its abbreviation; and

(III) the quantity of radioactivity at a specified date and time (the time may be omitted for radioactive drugs with a half life greater than 100 days); and

(ii) that each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution shall include the following:

(I) radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL;" and

(II) an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield.

(2) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs and shall have procedures for the use of the instrumentation. The licensee shall measure, by direct measurement or by a combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(A) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary;

(B) check each instrument for constancy and proper operation at the beginning of each day of use; and

(C) make, maintain, and retain records of the tests and checks required in this paragraph for inspection by the agency in accordance with subsection (mm) of this section.

(3) A licensee described in paragraph (1)(A)(iii) or (iv) of this subsection shall prepare radioactive drugs for medical use as defined in §289.256 of this title with the following provisions.

(A) Radioactive drugs shall be prepared by either an authorized nuclear pharmacist, as specified in subparagraphs (B) and (D) of this paragraph, or an individual under the supervision of an authorized nuclear pharmacist as specified in §289.256(s) of this title.

(B) A pharmacist shall be allowed to work as an authorized nuclear pharmacist if:

(i) the individual qualifies as an authorized nuclear pharmacist as defined in §289.256 of this title;

(ii) the individual meets the requirements specified in §289.256(k)(2) and (m) of this title, and the licensee has received from the agency, an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) the individual is designated as an authorized nuclear pharmacist in accordance with subparagraph (D) of this paragraph.

(C) The actions authorized in subparagraphs (A) and (B) of this paragraph are permitted in spite of more restrictive language in license conditions.

(D) A licensee may designate a pharmacist, as defined in §289.256 of this title, as an authorized nuclear pharmacist if:

(i) the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

(ii) the individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe or at all other pharmacies prior to the effective date of this rule as noticed by the NRC or the agency.

(E) The licensee shall provide the following to the agency:

(i) a copy of each individual's certification by a specialty board whose certification process has been recognized by the

NRC, agency, or an agreement state as specified in §289.256(k)(1) of this title with the written attestation signed by a preceptor as required by §289.256(k)(2)(C) of this title; or

(ii) the agency, NRC, or another agreement state license; or

(iii) the permit issued by a broad scope licensee or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(iv) documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe or at all other locations of use prior to the effective date of this rule as noticed by the NRC or the agency; and

(v) a copy of the Texas State Board of Pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, in accordance with subparagraph (B)(i) and (iii) of this paragraph, the individual to work as an authorized nuclear pharmacist.

(F) The radiopharmaceuticals for human use shall be processed and prepared according to instructions that are furnished by the manufacturer on the label attached to or in the FDA-accepted instructions in the leaflet or brochure that accompanies the generator or reagent kit.

(G) If the authorized nuclear pharmacist elutes generators or processes radioactive material with the reagent kit in a manner that deviates from instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit or in the accompanying leaflet or brochure, a complete description of the deviation shall be made and maintained for inspection by the agency in accordance with subsection (mm) of this section.

(4) Nothing in this subsection relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs.

(s) Specific licenses for the manufacture and commercial distribution of products containing depleted uranium for mass-volume applications.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture products and devices containing depleted uranium for use in accordance with §289.251(f)(3)(D) of this title or equivalent regulations of the NRC or an agreement state, will be issued if the agency approves the following information submitted by the applicant:

(A) the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the product or device to provide reasonable assurance that possession, use, or commercial distribution of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one year a radiation dose in excess of 10% of the limits specified in §289.202(f) of this title; and

(B) reasonable assurance is provided that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of a product or device whose unique benefits are questionable, the agency will issue a specific license in accordance with paragraph (1) of this subsection only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The agency may deny any application for a specific license in accordance with this subsection if the end use(s) of the product or device cannot be reasonably foreseen.

(4) Each person licensed in accordance with paragraph (1) of this subsection shall:

(A) maintain the level of quality control required by the license in the manufacture of the product or device, and in the installation of the depleted uranium into the product or device;

(B) label or mark each unit to:

(i) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(ii) state that the receipt, possession, use, and commercial distribution of the product or device are subject to a general license or the equivalent and the requirements of the NRC or of an agreement state;

(C) assure that before being installed in each product or device, the depleted uranium has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(D) furnish a copy of the following:

(i) the general license in §289.251(f)(3)(D) of this title to each person to whom the licensee commercially distributes depleted uranium in a product or device for use in accordance with the general license in §289.251(f)(3)(D) of this title;

(ii) the NRC's or agreement state's requirements equivalent to the general license in §289.251(f)(3)(D) of this title and a copy of the NRC's or agreement state's certificate; or

(iii) alternately, a copy of the general license in §289.251(f)(3)(D) of this title to each person to whom the licensee commercially distributes depleted uranium in a product or device for use in accordance with the general license of the NRC or an agreement state;

(E) report to the agency all commercial distributions of products or devices to persons for use in accordance with the general license in §289.251(f)(3)(D) of this title.

(i) The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is commercially distributed to the generally licensed person and shall include the following:

(I) identity of each general licensee by name and address;

(II) identity of an individual by name and/or position who may constitute a point of contact between the agency and the general licensee;

(III) the type and model number of devices commercially distributed; and

(IV) the quantity of depleted uranium contained in the product or device.

(ii) If no commercial distributions have been made to persons generally licensed in accordance with §289.251(f)(3)(D) of this title during the reporting period, the report shall so indicate;

(F) report to the NRC and each responsible agreement state agency all commercial distributions of industrial products or devices to persons for use in accordance with the general license in the NRC's or agreement state's equivalent requirements to §289.251(f)(3)(D) of this title. The report shall meet the provisions of subparagraph (E)(i) and (ii) of this paragraph; and

(G) make, maintain, and retain records including the name, address, and point of contact for each general licensee to whom the licensee commercially distributes depleted uranium in products or devices for use in accordance with the general license provided in §289.251(f)(3)(D) of this title or equivalent requirements of the NRC or any agreement state. The records shall be maintained for inspection by the agency in accordance with subsection (mm) of this section and shall include the date of each commercial distribution, the quantity of depleted uranium in each product or device commercially distributed, and compliance with the report requirements of this section.

(t) Specific licenses for the processing of loose radioactive material for manufacture and commercial distribution. In addition to the requirements in subsection (e) of this section, a license to process loose radioactive material for manufacture and commercial distribution of radioactive material to persons authorized to possess such radioactive material in accordance with this chapter will be issued if the agency approves the following information submitted by the applicant:

(1) radionuclides to be used, including the chemical and/or physical form and the maximum activity of each radionuclide;

(2) intended use of each radionuclide and the sealed sources and/or other products to be manufactured that includes:

(A) receipt of radioactive material;

(B) chemical or physical preparations;

(C) sealed source construction;

(D) final assembly or processing;

(E) quality assurance testing;

(F) quality control program;

(G) leak testing;

(H) American National Standards Institute (ANSI) testing procedures;

(I) transportation containers;

(J) shipping procedures; and

(K) disposition of unwanted or unused radioactive material;

(3) scaled drawings of the facility to include, but not be limited to:

(A) air filtration;

(B) ventilation system;

(C) plumbing; and

(D) radioactive material handling systems and, when applicable, remote handling hot cells;

(4) details of the environmental monitoring program; and

(5) documentation of training as specified in subsection (jj)(1) of this section for all personnel who will be handling radioactive materials.

(u) Specific licenses for other manufacture and commercial distribution of radioactive material. In addition to the requirements

in subsection (e) of this section, a license to manufacture and commercially distribute radioactive material to persons authorized to possess such radioactive material in accordance with these requirements will be issued if the agency approves the following information submitted by the applicant:

(1) the radionuclides to be used, including the chemical and/or physical form and the maximum activity of each radionuclide;

(2) the intended use of each radionuclide and the sealed sources and/or other products to be manufactured that includes:

- (A) receipt of radioactive material;
- (B) chemical or physical preparations;
- (C) sealed source construction;
- (D) final assembly or processing;
- (E) quality assurance testing;
- (F) quality control program;
- (G) leak testing;
- (H) ANSI testing procedures;
- (I) transportation containers;
- (J) shipping procedures; and
- (K) disposition of unwanted or unused radioactive material;

(3) sealed drawings of radioactive material handling systems; and

(4) documentation of training as specified in subsection (jj)(1) of this section for all personnel who will be handling radioactive material.

(v) Sealed source or device evaluation.

(1) Any manufacturer or initial distributor of a sealed source or device containing a sealed source shall submit a request to the agency for evaluation of radiation safety information about its product and for its registration.

(2) The request for review shall be sent to the agency in accordance with §289.201(k) of this title and shall be submitted in duplicate accompanied by the appropriate fee specified in §289.204 of this title.

(3) In order to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property, the request for evaluation of a sealed source or device shall include sufficient information about the:

- (A) design;
- (B) manufacture;
- (C) prototype testing;
- (D) quality control program;
- (E) labeling;
- (F) proposed uses; and
- (G) leak testing.

(4) The request for evaluation of a device shall also include sufficient information about:

- (A) installation;

- (B) service and maintenance;
- (C) operating and safety instructions; and
- (D) its potential hazards.

(5) The agency normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. Section 289.251(e)(1) - (3) of this title includes specific criteria that apply to certain exempt products and §289.251(f) of this title includes specific criteria applicable to certain generally licensed devices. This section includes specific provisions that apply to certain specifically licensed items.

(6) After completion of the evaluation, the agency issues a sealed source and device (SS & D) certificate of registration to the person making the request. The SS & D certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of SS & D certificate of registration.

(7) The person submitting the request for evaluation and SS & D certificate of registration of safety information about the product shall manufacture and distribute the product in accordance with:

(A) the statements and representations, including quality control program, contained in the request; and

(B) the provisions of the SS & D certificate of registration.

(8) Authority to manufacture or initially distribute a sealed source or device to specific licensees shall be provided in the license without the issuance of a SS & D certificate of registration in the following cases:

(A) calibration and reference sources shall contain no more than:

(i) 1 mCi (37 MBq) for beta and/or gamma emitting radionuclides; or

(ii) 10 µCi (0.37 MBq) for alpha emitting radionuclides; or

(B) the intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

(i) the intended recipients are licensed in accordance with this section or equivalent regulations of the NRC or any agreement state; or

(ii) the recipients are authorized for research and development; or

(iii) the sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 20 Ci (740 GBq) of tritium or 200 mCi (7.4 GBq) of any other radionuclide.

(9) After the SS & D certificate of registration is issued, the agency may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the agency will complete its evaluation in accordance with criteria specified in this section. The agency may request such additional information as it considers necessary to conduct its review and the SS & D certificate of registration holder shall provide the information as requested.

(10) Inactivation of SS & D certificate(s) of registration.

(A) An SS & D certificate of registration holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular SS & D certificate of registration issued by the agency shall request inactivation of the SS & D certificate of registration. Such a request shall be made to the agency by an appropriate method in accordance with §289.201(k) of this title and shall normally be made no later than 2 years after initial distribution of all of the source(s) or device(s) covered by the SS & D certificate of registration has ceased. However, if the SS & D certificate of registration holder determines that an initial transfer was in fact the last initial transfer more than 2 years after that transfer, the SS & D certificate of registration holder shall request inactivation of the SS & D certificate of registration within 90 days of this determination and briefly describe the circumstances of the delay.

(B) If a distribution license is to be terminated in accordance with subsection (y) of this section, the licensee shall request inactivation of its SS & D certificate of registration(s) associated with that distribution license before the agency will terminate the license. Such a request for inactivation of the SS & D certificate(s) of registration shall indicate that the license is being terminated and include the associated specific license number.

(C) A specific license to manufacture or initially transfer a source or device covered only by an inactivated SS & D certificate of registration no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices shall be in accordance with any conditions in the SS & D certificate of registration, including in the case of an inactive SS & D certificate of registration.

(w) Issuance of specific licenses.

(1) When the agency determines that an application meets the requirements of the Act and the rules of the agency, the agency will issue a specific license authorizing the proposed activity in such form and containing the conditions and limitations as the agency deems appropriate or necessary.

(2) The agency may incorporate in any license at the time of issuance, or thereafter by amendment, additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this section as the agency deems appropriate or necessary in order to:

(A) minimize danger to occupational and public health and safety and the environment;

(B) require reports and the keeping of records, and to provide for inspections of activities in accordance with the license as may be appropriate or necessary; and

(C) prevent loss or theft of radioactive material subject to this chapter.

(3) The agency may request, and the licensee shall provide, additional information after the license has been issued to enable the agency to determine whether the license should be modified in accordance with subsection (dd) of this section.

(x) Specific terms and conditions of licenses.

(1) Each license issued in accordance with this section shall be subject to the applicable provisions of the Act and to applicable rules, now or hereafter in effect, and orders of the agency.

(2) No license issued or granted in accordance with this section and no right to possess or utilize radioactive material granted by any license issued in accordance with this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and to applicable rules, now or hereafter in effect, and orders of the agency, and shall give its consent in writing.

(3) An application for transfer of license shall include:

(A) the identity, technical and financial qualifications of the proposed transferee; and

(B) financial assurance for decommissioning information required by subsection (gg) of this section.

(4) Each person licensed by the agency in accordance with this section shall confine use and possession of the radioactive material licensed to the locations and purposes authorized in the license. Radioactive material shall not be used or stored in residential locations unless specifically authorized by the agency.

(5) The licensee shall notify the agency, in writing within 15 calendar days, of any of the following changes:

(A) name;

(B) mailing address; or

(C) RSO.

(6) Each licensee shall notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by the licensee or its parent company, if the parent company is involved in the bankruptcy.

(7) The notification in paragraph (6) of this subsection shall include:

(A) the bankruptcy court in which the petition for bankruptcy was filed; and

(B) the date of the filing of the petition.

(8) A copy of the petition for bankruptcy shall be submitted to the agency along with the written notification.

(9) In making a determination whether to grant, deny, amend, renew, revoke, suspend, or restrict a license, the agency may consider the technical competence and compliance history of an applicant or holder of a license. After an opportunity for a hearing, the agency shall deny an application for a license, an amendment to a license, or renewal of a license if the applicant's compliance history reveals that three or more agency actions have been issued against the applicant, within the previous six years, that assess administrative or civil penalties against the applicant, or that revoke or suspend the license.

(10) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with §289.256 of this title. The licensee shall make, maintain, and retain

a record of the results of each test for inspection by the agency in accordance with subsection (mm) of this section.

(11) Licensees shall not hold radioactive waste, sources, or devices not authorized for disposal by decay in storage, and that are not in use for longer than 24 months following the last principal activity use. Sources and devices kept in standby for future use may be excluded from the 24-month time limit if the agency approves a plan for future use. A plan for an alternative disposal timeframe may be submitted by the licensee if the 24-month time limit cannot be met. Licensees shall submit plans to the agency at least 30 days prior to the end of the 24 months of nonuse.

(y) Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(1) Except as provided in paragraph (2) of this subsection and subsection (z)(2) of this section, each specific license expires at the end of the day, in the month and year stated in the license.

(2) Expiration of the specific license does not relieve the licensee of the requirements of this chapter.

(3) All license provisions continue in effect beyond the expiration date, with respect to possession of radioactive material until the agency notifies the former licensee in writing that the provisions of the license are no longer binding. During this time, the former licensee shall:

(A) be limited to actions involving radioactive material that are related to decommissioning; and

(B) continue to control entry to restricted areas until the location(s) is suitable for release for unrestricted use in accordance with the requirements in §289.202(ddd) of this title.

(4) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the agency in writing and either begin decommissioning a site, or any separate building or outdoor area that contains residual radioactivity, so that the building and/or outdoor area is suitable for release in accordance with §289.202(eee) of this title, or submit within 12 months of notification a decommissioning plan, if required by paragraph (7) of this subsection, and begin decommissioning upon approval of that plan if:

(A) the license has expired or has been revoked in accordance with this subsection or subsection (dd) of this section;

(B) the licensee has decided to permanently cease principal activities, as defined in §289.201(b) of this title, at the entire site or in any separate building or outdoor area;

(C) no principal activities at an entire site as specified in the license have been conducted for a period of 24 months; or

(D) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with §289.202(eee) of this title.

(5) Coincident with the notification required by paragraph (4) of this subsection, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee in accordance with subsection (gg) of this section in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance shall be increased, or may be decreased, as appropriate, with agency approval, to cover the detailed cost estimate for decommissioning established in accordance with paragraph (10)(E) of this subsection.

(6) The agency may grant a request to delay or postpone initiation of the decommissioning process if the agency determines that such relief is not detrimental to the occupational and public health and safety and is otherwise in the public interest. The request shall be submitted no later than 30 days before notification in accordance with paragraph (4) of this subsection. The schedule for decommissioning set forth in paragraph (4) of this subsection may not commence until the agency has made a determination on the request.

(7) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(A) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(B) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(C) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(D) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(8) The agency may approve an alternate schedule for submittal of a decommissioning plan required in accordance with paragraph (4) of this subsection if the agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the occupational and public health and safety and is otherwise in the public interest.

(9) The procedures listed in paragraph (7) of this subsection may not be carried out prior to approval of the decommissioning plan.

(10) The proposed decommissioning plan for the site or separate building or outdoor area shall include the following:

(A) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(B) a description of planned decommissioning activities;

(C) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(D) a description of the planned final radiation survey;

(E) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning; and

(F) for decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in paragraph (15) of this subsection.

(11) The proposed decommissioning plan will be approved by the agency if the information in the plan demonstrates that the decommissioning will be completed as soon as practicable and that the

health and safety of workers and the public will be adequately protected.

(12) Except as provided in paragraph (14) of this subsection, licensees shall complete decommissioning of the site or separate building or outdoor areas as soon as practicable but no later than 24 months following the initiation of decommissioning.

(13) Except as provided in paragraph (14) of this subsection, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(14) The agency may approve a request for an alternate schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the agency determines that the alternative is warranted by consideration of the following:

(A) whether it is technically feasible to complete decommissioning within the allotted 24 month period;

(B) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24 month period;

(C) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(D) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(E) other site-specific factors that the agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(15) As the final step in decommissioning, the licensee shall do the following:

(A) certify the disposition of all licensed material, including accumulated wastes; and

(B) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in accordance with the radiological requirements for license termination specified in §289.202(ddd) of this title. The licensee shall do the following, as appropriate:

(i) report the following levels:

(I) gamma radiation in units of microroentgen per hour ($\mu\text{R/hr}$) (millisieverts per hour (mSv/hr)) at 1 meter (m) from surfaces;

(II) radioactivity, including alpha and beta, in units of disintegrations per minute (dpm) or microcuries (μCi) (megabecquerels (MBq)) per 100 square centimeters (cm^2) for surfaces;

(III) μCi (MBq) per milliliter for water; and

(IV) picocuries (pCi) (becquerels (Bq)) per gram (g) for solids such as soils or concrete; and

(ii) specify the manufacturer's name and model and serial number of survey instrument(s) used and certify that each instru-

ment is properly calibrated in accordance with §289.202(p) of this title and tested.

(16) The agency will provide written notification to specific licensees, including former licensees with provisions continued in effect beyond the expiration date in accordance with paragraph (3) of this subsection, that the provisions of the license are no longer binding. The agency will provide such notification when the agency determines that:

(A) radioactive material has been properly disposed;

(B) reasonable effort has been made to eliminate residual radioactive contamination, if present;

(C) a radiation survey has been performed that demonstrates that the premises are suitable for release in accordance with the radiological requirements for license termination specified in §289.202(ddd) of this title, or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the radiological requirements for license termination specified in §289.202(ddd) of this title; and

(D) any outstanding fees in accordance with §289.204 of this title are paid and any outstanding notices of violations of this chapter or of license conditions are resolved.

(17) Each licensee shall submit to the agency all records required by §289.202(nn)(2) of this title before the license is terminated.

(z) Renewal of licenses.

(1) Requests for renewal of specific licenses shall be filed in accordance with subsection (d)(1) - (3) and (5) - (7) of this section. In any application for renewal, the applicant may incorporate drawings by clear and specific reference (for example, title, date and unique number of drawing), if no modifications have been made since previously submitted.

(2) In any case in which a licensee, not less than 30 days prior to expiration of an existing license, has filed a request in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the request has been finally determined by the agency. In any case in which a licensee, not more than 90 days after the expiration of an existing license, has filed a request in proper form for renewal or for a new license authorizing the same activities, the agency may reinstate the license and extend the expiration until the request has been finally determined by the agency. The requirements in this subsection are subject to the provisions of Government Code, §2001.054.

(3) An application for technical renewal of a license will be approved if the agency determines that the requirements of subsection (e) of this section have been satisfied.

(aa) Amendment of licenses at request of licensee.

(1) Requests for amendment of a license shall be filed in accordance with subsection (d)(1) - (3) of this section shall be signed by management or the RSO, and shall specify the respects in which the licensee desires a license to be amended and the grounds for the amendment.

(2) Requests for amendments to delete a subsite from a license shall be filed in accordance with subsections (d)(1) and (2) and (y)(3) and (15) of this section.

(bb) Agency action on requests to renew or amend. In considering a request by a licensee to renew or amend a license, the agency will apply the criteria in subsection (e) of this section as applicable.

(cc) Transfer of material.

(1) No licensee shall transfer radioactive material except as authorized in accordance with this chapter. This subsection does not include transfer for commercial distribution.

(2) Except as otherwise provided in a license and subject to the provisions of paragraphs (3) and (4) of this subsection, any licensee may transfer radioactive material:

(A) to the agency (A licensee may transfer material to the agency only after receiving prior approval from the agency);

(B) to the United States Department of Energy (DOE);

(C) to any person exempt from this section to the extent permitted in accordance with such exemption;

(D) to any person authorized to receive such material in accordance with the terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the NRC, or any agreement state, or to any person otherwise authorized to receive such material by the federal government or any agency of the federal government, the agency, or any agreement state; or

(E) as otherwise authorized by the agency in writing.

(3) Before transferring radioactive material to a specific licensee of the agency, the NRC, or any agreement state, or to a general licensee who is required to register with the agency, the NRC, or any agreement state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(4) The following methods for the verification required by paragraph (3) of this subsection are acceptable.

(A) The transferor may possess and have read a current copy of the transferee's specific license.

(B) When a current copy of the transferee's specific license described in subparagraph (A) of this paragraph is not readily available or when a transferor desires to verify that information received is correct or up-to-date, the transferor may obtain and record confirmation from the agency, the NRC, or any agreement state that the transferee is licensed to receive the radioactive material.

(5) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of subsection (ff) of this section.

(6) Requirements for transfer of small quantities of source material.

(A) An application for a specific license to initially transfer source material for use in accordance with §289.251(f)(3) of this title; Title 10, CFR, §40.22; or equivalent regulations of any agreement state, will be approved if:

(i) the applicant satisfies the general requirements specified in subsection (e) of this section; and

(ii) the applicant submits adequate information on, and the agency approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

(B) Quality control, labeling, safety instructions, and records and reports. Each person licensed under subparagraph (A) of this paragraph shall:

(i) label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."

(ii) ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(iii) provide the information specified in this clause to each person to whom source material is transferred for use under §289.251(f)(3) of this title; Title 10, CFR, §40.22; or equivalent regulations of any agreement state. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(I) a copy, as applicable, of §289.251(f)(3) of this title; Title 10, CFR, §40.22; or the equivalent agreement state regulation that applies; and of this subsection; Title 10, CFR, §40.51; or the equivalent agreement state regulations that apply; and

(II) appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(iv) report transfers as follows:

(I) File a report with the agency and the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The report shall include the following information:

(-a-) the name, address, and license number of the person who transferred the source material;

(-b-) for each general licensee under §289.251(f)(3) of this title; Title 10, CFR, §40.22; or equivalent regulations of any agreement state to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(-c-) the total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(II) File a report with each responsible agreement state agency that identifies all persons, operating under §289.251(f)(3) of this title; Title 10, CFR, §40.22, or equivalent regulations of any agreement state to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state being reported to:

(-a-) the name, address, and license number of the person who transferred the source material; and

(-b-) the name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(-c-) the total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the agreement state.

(III) The following are to be submitted to the agency by January 31 of each year:

(-a-) each report required by subclauses (I) and (II) of this clause covering all transfers for the previous calendar year;

(-b-) if no transfers were made during the current period to persons generally licensed in accordance with §289.251(f)(3) of this title; Title 10, CFR, §40.22; or equivalent regulations of any agreement state, a report to the agency indicating so; and

(-c-) if no transfers have been made to general licensees in a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state upon request of that agency; and

(v) maintain all information that supports the reports required by this subparagraph concerning each transfer to a general licensee for inspection by the agency in accordance with subsection (mm) of this section.

(dd) Modification, suspension, and revocation of licenses.

(1) The terms and conditions of all licenses shall be subject to revision or modification. A license may be modified, suspended or revoked by reason of amendments to the Act, by reason of rules in this chapter, or orders issued by the agency.

(2) Any license may be revoked, suspended, or modified, in whole or in part, for any of the following:

(A) any material false statement in the application or any statement of fact required under provisions of the Act;

(B) conditions revealed by such application or statement of fact or any report, record, or inspection, or other means that would warrant the agency to refuse to grant a license on an original application;

(C) violation of, or failure to observe any of the terms and conditions of the Act, this chapter, the license, or order of the agency; or

(D) existing conditions that constitute a substantial threat to the public health or safety or the environment.

(3) Each specific license revoked by the agency ends at the end of the day on the date of the agency's final determination to revoke the license, or on the revocation date stated in the determination, or as otherwise provided by the agency order.

(4) Except in cases in which the occupational and public health or safety requires otherwise, no license shall be suspended or revoked unless, prior to the institution of proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been afforded an opportunity to demonstrate compliance with all lawful requirements.

(ee) Reciprocal recognition of licenses.

(1) Subject to this section, any person who holds a specific license from the NRC or any agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is granted a general license to conduct the activities authorized in such licensing document within the State of Texas provided that:

(A) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(B) the out-of-state licensee notifies the agency in writing at least three working days prior to engaging in such activity. If, for a specific case, the three-working-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities in accordance with the general license provided in this subsection. Such notification shall include:

(i) the exact location, start date, duration, and type of activity to be conducted;

(ii) the identification of the radioactive material to be used;

(iii) the name(s) and in-state address(es) of the individual(s) performing the activity;

(iv) a copy of the applicant's pertinent license;

(v) a copy of the licensee's operating, safety, and emergency procedures; and

(vi) a fee as specified in §289.204 of this title;

(C) the out-of-state licensee complies with all applicable rules of the agency and with all the terms and conditions of the licensee's licensing document, except any such terms and conditions that may be inconsistent with applicable rules of the agency;

(D) the out-of-state licensee supplies such other information as the agency may request;

(E) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used in accordance with the general license provided in this subsection except by transfer to a person:

(i) specifically licensed by the agency, the NRC, or any agreement state to receive such material, or

(ii) exempt from the requirements for a license for such material in accordance with §289.251(e)(1) of this title; and

(F) the out-of-state licensee shall have the following documents in their possession at all times when conducting work in Texas, and make them available for agency review upon request:

(i) a copy of the agency letter granting the licensee reciprocal recognition of their out-of-state license;

(ii) a copy of the licensee's operating and emergency procedures;

(iii) a copy of the licensee's radioactive material license;

(iv) a copy of all applicable sections of 25 TAC, Chapter 289; and

(v) a copy of the completed RC Form 252-3 notifying the agency of the licensee's intent to work in Texas.

(2) In addition to the provisions of paragraph (1) of this subsection, any person who holds a specific license issued by the NRC or any agreement state authorizing the holder to manufacture, transfer, install, or service the device described in §289.251(f)(4)(H) of this title, within areas subject to the jurisdiction of the licensing body, is granted a general license to install, transfer, demonstrate, or service the device in the State of Texas provided that:

(A) the person files a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in the State of Texas. Each report shall identify by name and address, each general licensee to whom the device is transferred, the type of device transferred by manufacturer's name, model and serial number of the device, and serial number of the sealed source, and the quantity and type of radioactive material contained in the device;

(B) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to the person by the NRC or any agreement state;

(C) the person assures that any labels required to be affixed to the device in accordance with requirements of the authority that licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(D) the holder of the specific license furnishes to each general licensee to whom the holder of the specific license transfers the device, or on whose premises the holder of the specific license installs the device, a copy of the general license contained in §289.251(f)(4)(H) of this title.

(3) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed in accordance with the licensing document, upon determining that the action is necessary in order to prevent undue hazard to occupational and public health and safety and the environment.

(ff) Preparation of radioactive material for transport. Requirements for the preparation of radioactive material for transport are specified in §289.257 of this title.

(gg) Financial assurance and record keeping for decommissioning.

(1) The applicant for a specific license or renewal of a specific license, or holder of a specific license, authorizing the possession and use of radioactive material shall submit and receive written authorization for a decommissioning funding plan as described in paragraph (4) of this subsection in an amount sufficient to allow the agency to engage a third party to decommission the site(s) specified on the license for the following situations:

(A) when unsealed radioactive material requested or authorized on the license, with a half-life greater than 120 days, is in quantities exceeding 10^5 times the applicable quantities set forth in subsection (jj)(2) of this section;

(B) when a combination of the unsealed radionuclides requested or authorized on the license, with a half-life greater than 120 days, results in the R of the radionuclides divided by 10^5 being greater than 1 (unity rule), where R is defined as the sum of the ratios of the quantity of each radionuclide to the applicable value in subsection (jj)(2) of this section;

(C) when sealed sources or plated foils requested or authorized on the license, with a half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in subsection (jj)(2) of this section (or when a combination of isotopes is involved if R, as defined in this subsection, divided by 10^{12} is greater than 1), shall submit a decommissioning funding plan as described in paragraph (4) of this subsection; or

(D) when radioactive material requested or authorized on the license is in quantities more than 100 mCi (3.7 gigabecquerels (GBq)) of source material in a readily dispersible form.

(2) The applicant for a specific license or renewal of a specific license or the holder of a specific license authorizing possession and use of radioactive material as specified in paragraph (3) of this subsection shall either:

(A) submit a decommissioning funding plan as described in paragraph (4) of this subsection in an amount sufficient to allow the agency to engage a third party to decommission the site(s) specified on the license; or

(B) submit financial assurance for decommissioning in the amount in accordance with paragraph (3) of this subsection using one of the methods described in paragraph (6) of this subsection in

an amount sufficient to allow the agency to engage a third party to decommission the site(s) specified on the license

(3) The required amount of financial assurance for decommissioning is determined by the quantity of material authorized by the license and is determined as follows:

(A) \$1,125,000 for quantities of material greater than 10^4 but less than or equal to 10^5 times the applicable quantities in subsection (jj)(2) of this section in unsealed form. (For a combination of radionuclides, if R, as defined in paragraph (1) of this subsection, divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1);

(B) \$225,000 for quantities of material greater than 103 but less than or equal to 104 times the applicable quantities in subsection (jj)(2) of this section in unsealed form. (For a combination of radionuclides, if R, as defined in paragraph (1) of this subsection, divided by 103 is greater than 1 but R divided by 104 if less than or equal to 1);

(C) \$113,000 for quantities of material greater than 1010 but less than or equal to 1012 times the applicable quantities in subsection (jj)(2) of this section in sealed sources or plated foils. (For a combination of radionuclides, if R, as defined in paragraph (1) of this subsection, divided by 1010 is greater than 1, but R divided by 1012 is less than or equal to 1); or

(D) \$225,000 for quantities of source material greater than 10 mCi (0.37 GBq) but less than or equal to 100 mCi (3.7 GBq) in a readily dispersible form.

(4) Each decommissioning funding plan shall:

(A) be submitted for review and approval and shall contain the following:

(i) a detailed cost estimate for decommissioning in an amount reflecting:

(I) the cost of an independent contractor to perform all decommissioning activities;

(II) the cost of meeting the criteria of §289.202(ddd)(2) of this title for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of §289.202(ddd)(3) of this title, the cost estimate may be based on meeting the criteria of §289.202(ddd)(3) of this title;

(III) the volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(IV) an adequate contingency factor.

(ii) identification of and justification for using the key assumptions contained in the detailed cost estimate;

(iii) a description of the method of assuring funds for decommissioning from paragraph (5) of this subsection, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) a signed original of the financial instrument obtained to satisfy the requirements of paragraph (5) of this subsection (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning); and

(B) at the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan, be resubmitted

with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan shall update the information submitted with the original or prior approved plan, and shall specifically consider the effect of the following events on decommissioning costs:

- (i) spills of radioactive material producing additional residual radioactivity in onsite subsurface material;
- (ii) waste inventory increasing above the amount previously estimated;
- (iii) waste disposal costs increasing above the amount previously estimated;
- (iv) facility modifications;
- (v) changes in authorized possession limits;
- (vi) actual remediation costs that exceed the previous cost estimate;
- (vii) onsite disposal; and
- (viii) use of a settling pond.

(5) Financial assurance in conjunction with a decommissioning funding plan shall be submitted as follows:

(A) for an applicant for a specific license, financial assurance as described in paragraph (6) of this subsection, may be obtained after the application has been approved and the license issued by the agency, but shall be submitted to the agency prior to receipt of licensed material; or

(B) for an applicant for renewal of a specific license, or a holder of a specific license, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (6) of this subsection shall be submitted with the decommissioning funding plan.

(6) Financial assurance for decommissioning shall be provided by one or more of the following methods. The financial instrument obtained shall be continuous for the term of the license in a form prescribed by the agency. The applicant or licensee shall obtain written approval of the financial instrument or any amendment to it from the agency.

(A) Prepayment. Prepayment is the deposit into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(B) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in subsection (jj)(3) of this section. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in subsection (jj)(4) of this section. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in subsection (jj)(5) of this section. For nonprofit entities,

such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in subsection (jj)(6) of this section. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning shall contain the following conditions.

(i) The surety method or insurance shall be opened or, if written for a specified term, such as five years, shall be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance shall also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance shall be payable in the State of Texas to the Radiation and Perpetual Care Account.

(iii) The surety method or insurance shall remain in effect until the agency has terminated the license.

(C) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions shall be in accordance with subparagraph (B) of this paragraph.

(D) In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount in accordance with paragraph (4) of this subsection, and indicating that funds for decommissioning will be obtained when necessary.

(E) When a governmental entity is assuming custody and ownership of a site, there shall be an arrangement that is deemed acceptable by such governmental entity.

(7) Each person licensed in accordance with this section shall make, maintain, and retain records of information important to the safe and effective decommissioning of the facility in an identified location for inspection by the agency in accordance with §289.252(mm) of this section. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the agency considers important to decommissioning consists of the following:

(A) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas, as in the case of possible seepage into porous materials such as concrete. These records shall include any known information on identification of involved nuclides, quantities, forms, and concentrations;

(B) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used

and/or stored, and of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations;

(C) except for areas containing only sealed sources (provided the sealed sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

(i) all areas designated and formerly designated as restricted areas as defined in §289.201(b) of this title;

(ii) all areas outside of restricted areas that require documentation under subparagraph (A) of this paragraph; and

(iii) all areas outside of restricted areas where current and previous wastes have been buried as documented in accordance with §289.202(tt) of this title; and

(D) records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds.

(8) Any licensee who has submitted an application before January 1, 1995, for renewal of license in accordance with this section shall provide financial assurance for decommissioning in accordance with paragraphs (1) and (2) of this subsection.

(hh) Emergency plan for responding to a release.

(1) A new or renewal application for each specific license to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in subsection (jj)(7) of this section shall contain either:

(A) an evaluation showing that the maximum dose to a person offsite due to a release of radioactive material would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

(B) an emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted in accordance with paragraph (1)(A) of this subsection:

(A) the radioactive material is physically separated so that only a portion could be involved in an accident;

(B) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(C) the release fraction in the respirable size range would be lower than the release fraction in subsection (jj)(7) of this section due to the chemical or physical form of the material;

(D) the solubility of the radioactive material would reduce the dose received;

(E) facility design or engineered safety features in the facility would cause the release fraction to be lower than that in subsection (jj)(7) of this section;

(F) operating restrictions or procedures would prevent a release fraction as large as that in subsection (jj)(7) of this section; or

(G) other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted in accordance with paragraph (1)(B) of this subsection shall include the following information.

(A) Facility description. A brief description of the licensee's facility and area near the site.

(B) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(C) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(D) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(E) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(F) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(G) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the agency; also, responsibilities for developing, maintaining, and updating the plan.

(H) Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency. These reporting requirements do not supersede or release licensees from complying with the requirements in accordance with the Emergency Planning and Community Right-to-Know-Act of 1986, Title III, Publication L. 99-499 or other state or federal reporting requirements.

(I) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the agency.

(J) Training. A brief description of the frequency, performance objectives, and plans for the training that the licensee will provide workers on how to respond to an emergency, including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(K) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(L) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations at intervals not to exceed three months and biennial onsite exercises to test response to simulated emergencies. Communications checks with offsite response organizations shall include the check and update of

all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises shall use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.

(M) Hazardous chemicals. A certification that the applicant has met its responsibilities in accordance with the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Publication L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. The licensee shall provide any comments received within the 60 days to the agency with the emergency plan.

(ii) Physical protection of category 1 and category 2 quantities of radioactive material.

(1) Specific exemptions. A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of paragraphs (2) - (23) of this subsection, except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kilograms (4,409 pounds) is not exempt from the requirements of this subsection. The licensee shall implement the following requirements to secure the radioactive waste:

(A) use continuous physical barriers that allow access to the radioactive waste only through established access control points;

(B) use a locked door or gate with monitored alarm at the access control point;

(C) assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

(D) immediately notify the local law enforcement agency (LLEA) and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

(2) Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material.

(A) General.

(i) Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of this paragraph and paragraphs (3) - (8) of this subsection.

(ii) An applicant for a new license and each licensee that would become subject to the requirements of this paragraph and paragraphs (3) - (8) of this subsection upon application for modification of its license shall implement the requirements of this paragraph and paragraphs (3) - (8) of this subsection, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(iii) Any licensee that has not previously implemented the security orders or been subject to this paragraph and paragraphs (3) - (8) of this subsection shall implement the provisions of these paragraphs before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(B) General performance objective. The licensee's access authorization program must ensure that the individuals specified in subparagraph (C)(i) of this paragraph are trustworthy and reliable.

(C) Applicability.

(i) Licensees shall subject the following individuals to an access authorization program:

(I) any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

(II) reviewing officials.

(ii) Licensees need not subject the categories of individuals listed in paragraph (6)(A)(i) - (xiii) of this subsection to the investigation elements of the access authorization program.

(iii) Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

(iv) Licensees may include individuals needing access to safeguards information-modified handling in accordance with Title 10, CFR, Part 73, in the access authorization program under this paragraph and paragraphs (3) - (8) of this subsection.

(3) Access authorization program requirements.

(A) Granting unescorted access authorization.

(i) Licensees shall implement the requirements of paragraph (2), this paragraph, and paragraphs (4) - (8) of this subsection for granting initial or reinstated unescorted access authorization.

(ii) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by paragraph (10)(C) of this subsection before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

(B) Reviewing officials.

(i) Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

(ii) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official must be taken by a law enforcement agency, federal or state agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with paragraph (4)(B) of this subsection.

(iii) Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information or safeguards informa-

tion-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

(iv) Reviewing officials cannot approve other individuals to act as reviewing officials.

(v) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(I) the individual has undergone a background investigation that included fingerprinting and a Federal Bureau of Investigation (FBI) criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(II) the individual is subject to a category listed in paragraph (6)(A) of this subsection.

(C) Informed consent.

(i) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of paragraph (4)(B) of this subsection. A signed consent must be obtained prior to any reinvestigation.

(ii) The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

(I) if an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

(II) the withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

(D) Personal history disclosure. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by paragraph (2), this paragraph, and paragraphs (4) - (8) of this subsection is sufficient cause for denial or termination of unescorted access.

(E) Determination basis.

(i) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of paragraph (2), this paragraph, and paragraphs (4) - (8) of this subsection.

(ii) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of paragraph (2), this paragraph, and paragraphs (4) - (8) of this subsection and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

(iii) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(iv) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.

(v) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall:

(I) remove the person from the approved list as soon as possible, but no later than 7 working days; and

(II) take prompt measures to ensure that the individual is unable to have unescorted access to the material.

(F) Procedures. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must:

(i) include provisions for the notification of individuals who are denied unescorted access;

(ii) include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization; and

(iii) contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

(G) Right to correct and complete information.

(i) Prior to any final adverse determination, licensees shall provide each individual subject to paragraph (2), this paragraph, and paragraphs (4) - (8) of this subsection with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for inspection by the agency in accordance with subsection (mm) of this section.

(ii) If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in Title 28, CFR, §§16.30 - 16.34. In the latter case, the FBI will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees shall provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

(H) Records. The licensee shall make, maintain, and retain the following records/documents for inspection by the agency in accordance with subsection (mm) of this section. The licensee shall maintain superseded versions or portions of the following records/documents for inspection by the agency in accordance with subsection (mm) of this section:

(i) documentation regarding the trustworthiness and reliability of individual employees;

(ii) a copy of the current access authorization program procedures; and

(iii) the current list of persons approved for unescorted access authorization.

(4) Background investigations.

(A) Initial investigation. Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the 7 years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation must include at a minimum:

(i) fingerprinting and an FBI identification and criminal history records check in accordance with paragraph (5) of this subsection;

(ii) verification of true identity. Licensees shall:

(I) verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who he or she claims to be;

(II) review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information;

(III) document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with paragraph (7) of this subsection;

(IV) certify in writing that the identification was properly reviewed; and

(V) maintain the certification and all related documents for inspection by the agency in accordance with subsection (mm) of this section;

(iii) employment history verification. Licensees shall:

(I) complete an employment history verification, including military history; and

(II) verify the individual's employment with each previous employer for the most recent 7 years before the date of application;

(iv) verification of education. Licensees shall verify that the individual participated in the education process during the claimed period;

(v) character and reputation determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference

checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks as specified in paragraphs (2) and (3), this paragraph, and paragraphs (5) - (8) of this subsection must be limited to whether the individual has been and continues to be trustworthy and reliable;

(vi) the licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (e.g., seek references not supplied by the individual); and

(vii) if a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

(B) Grandfathering.

(i) Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material as specified in the fingerprint orders may continue to have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.

(ii) Individuals who have been determined to be trustworthy and reliable in accordance with Title 10, CFR, Part 73, or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under Title 10, CFR, Part 73, or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.

(C) Reinvestigations. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with paragraph (5) of this subsection. The reinvestigations must be completed within 10 years of the date on which these elements were last completed.

(5) Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material.

(A) General performance objective and requirements.

(i) Except for those individuals listed in paragraph (6) of this subsection and those individuals grandfathered under paragraph (4)(B) of this subsection, each licensee subject to the requirements of paragraphs (2) - (4), this paragraph, and paragraphs (6) - (8) of this subsection shall:

(I) fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material;

(II) transmit all collected fingerprints to the NRC for transmission to the FBI; and

(III) use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.

(ii) The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.

(iii) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:

(I) the individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and

(II) the previous access was terminated under favorable conditions.

(iv) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted in accordance with paragraphs (2) - (4), this paragraph, and paragraphs (6) - (8) of this subsection, the fingerprint orders, or Title 10, CFR, Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the requirements of paragraph (7)(C) of this subsection.

(v) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

(B) Prohibitions.

(i) Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(I) an arrest more than one year old for which there is no information of the disposition of the case; or

(II) an arrest that resulted in dismissal of the charge or an acquittal.

(ii) Licensees may not use information received from a criminal history records check obtained under paragraphs (2) - (4), this paragraph, and paragraphs (6) - (8) of this subsection in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

(C) Procedures for processing of fingerprint checks.

(i) For the purpose of complying with paragraphs (2) - (4), this paragraph, and paragraphs (6) - (8) of this subsection, licensees shall use an appropriate method listed in Title 10, CFR, §37.7, to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal

History Program/Mail Stop TWB-05 B32M, Rockville, Maryland 20852-2738, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (630) 829-9565, or by email to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <http://www.nrc.gov/site-help/e-submittals.html>.

(ii) Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at (301) 492-3531.) Combined payment for multiple applications is acceptable. The NRC publishes the amount of the fingerprint check application fee on the NRC's public website. (To find the current fee amount, go to the Electronic Submittals page at <http://www.nrc.gov/site-help/e-submittals.html> and see the link for the Criminal History Program under Electronic Submission Systems.)

(iii) The NRC will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

(6) Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.

(A) Fingerprinting, and the identification and criminal history records checks required by Section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:

(i) an employee of the NRC or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(ii) a member of Congress;

(iii) an employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(iv) the governor of a state or his or her designated state employee representative;

(v) federal, state, or local law enforcement personnel;

(vi) state radiation control program directors and state homeland security advisors or their designated state employee representatives;

(vii) agreement state employees conducting security inspections on behalf of the NRC under an agreement executed as specified in §274.i. of the Atomic Energy Act;

(viii) representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

(ix) emergency response personnel who are responding to an emergency;

(x) commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;

(xi) package handlers at transportation facilities such as freight terminals and railroad yards;

(xii) any individual who has an active federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that granted the federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall maintain this documentation for inspection by the agency in accordance with subsection (mm) of this section; and

(xiii) any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall maintain and retain the documentation for inspection by the agency in accordance with subsection (mm) of this section.

(B) Fingerprinting, and the identification and criminal history records checks required by Section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last 5 years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall maintain this documentation for inspection by the agency in accordance with subsection (mm) of this section. These programs include, but are not limited to:

(i) National Agency Check;

(ii) Transportation Worker Identification Credentials (TWIC) under Title 49, CFR, Part 1572;

(iii) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under Title 27, CFR, Part 555;

(iv) Health and Human Services security risk assessments for possession and use of select agents and toxins under Title 42, CFR, Part 73;

(v) Hazardous Material security threat assessment for hazardous material endorsement to commercial drivers license under Title 49, CFR, Part 1572; and

(vi) Customs and Border Protection's Free and Secure Trade (FAST) Program.

(7) Protection of information.

(A) Each licensee who obtains background information on an individual under paragraphs (2) - (6), this paragraph, or paragraph (8) of this subsection shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

(B) The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the

process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

(C) The personal information obtained on an individual from a background investigation may be provided to another licensee:

(i) upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

(ii) the recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

(D) The licensee shall make background investigation records obtained under paragraphs (2) - (6), this paragraph, and paragraph (8) of this subsection available for examination by an authorized representative of the agency to determine compliance with the regulations and laws.

(E) The licensee shall maintain all fingerprint and criminal history records on an individual (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, for inspection by the agency in accordance with subsection (mm) of this section.

(8) Access authorization program review.

(A) Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of paragraphs (2) - (7) and this paragraph of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall review the access program content and implementation at least every 12 months.

(B) The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(C) Review records must be maintained for inspection by the agency in accordance with subsection (mm) of this section.

(9) Security program.

(A) Applicability.

(i) Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this paragraph and paragraphs (10) - (17) of this subsection.

(ii) An applicant for a new license and each licensee that would become newly subject to the requirements of this paragraph and paragraphs (10) - (17) of this subsection upon application for modification of its license shall implement the requirements of this paragraph and paragraphs (10) - (17) of this subsection, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(iii) Any licensee that has not previously implemented the security orders or been subject to the provisions of this paragraph and paragraphs (10) - (17) of this subsection shall provide written notification to the agency at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(B) General performance objective. Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

(C) Program features. Each licensee's security program must include the program features, as appropriate, described in paragraphs (10) - (16) of this subsection.

(10) General security program requirements.

(A) Security plan.

(i) Each licensee identified in paragraph (9)(A) of this subsection shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by paragraph (9), this paragraph, and paragraphs (11) - (17) of this subsection. The security plan must, at a minimum:

(I) describe the measures and strategies used to implement the requirements of paragraph (9), this paragraph, and paragraphs (11) - (17) of this subsection; and

(II) identify the security resources, equipment, and technology used to satisfy the requirements of paragraph (9), this paragraph, and paragraphs (11) - (17) of this subsection.

(ii) The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

(iii) A licensee shall revise its security plan as necessary to ensure the effective implementation of agency and NRC requirements. The licensee shall ensure that:

(I) the revision has been reviewed and approved by the individual with overall responsibility for the security program; and

(II) the affected individuals are instructed on the revised plan before the changes are implemented.

(iv) The licensee shall maintain a copy of the current security plan as a record for inspection by the agency in accordance with subsection (mm) of this section. If any portion of the plan is superseded, the licensee shall maintain the superseded material for inspection by the agency in accordance with subsection (mm) of this section.

(B) Implementing procedures.

(i) The licensee shall develop and maintain written procedures that document how the requirements of paragraph (9), this paragraph, and paragraphs (11) - (17) of this subsection and the security plan will be met.

(ii) The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

(iii) The licensee shall maintain a copy of the current procedure as a record for inspection by the agency in accordance with

subsection (mm) of this section. Superseded portions of the procedure shall be maintained for inspection by the agency in accordance with subsection (mm) of this section.

(C) Training.

(i) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

(I) the licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;

(II) the responsibility to report promptly to the licensee any condition that causes or may cause a violation of the requirements of the agency;

(III) the responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and

(IV) the appropriate response to security alarms.

(ii) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

(iii) Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:

(I) review of the training requirements of this subparagraph of this paragraph and any changes made to the security program since the last training;

(II) reports on any relevant security issues, problems, and lessons learned;

(III) relevant results of inspections by the agency; and

(IV) relevant results of the licensee's program review and testing and maintenance.

(iv) The licensee shall maintain records of the initial and refresher training for inspection by the agency in accordance with subsection (mm) of this section. The training records shall include:

(I) the dates of the training;

(II) the topics covered;

(III) a list of licensee personnel in attendance; and

(IV) any related information.

(D) Protection of information.

(i) Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

(ii) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan and implementing procedures.

(iii) Before granting an individual access to the security plan or implementing procedures, licensees shall:

(I) evaluate an individual's need to know the security plan or implementing procedures; and

(II) if the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in paragraph (4)(A)(ii) - (vii) of this subsection.

(iv) Licensees need not subject the following individuals to the background investigation elements for protection of information:

(I) the categories of individuals listed in paragraph (6)(A)(i) of this subsection; or

(II) security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in paragraph (4)(A)(ii) - (vii) of this subsection, has been provided by the security service provider.

(v) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan or implementing procedures.

(vi) Licensees shall maintain a list of persons currently approved for access to the security plan or implementing procedures. When a licensee determines that a person no longer needs access to the security plan or implementing procedures or no longer meets the access authorization requirements for access to the information, the licensee shall:

(I) remove the person from the approved list as soon as possible, but no later than 7 working days; and

(II) take prompt measures to ensure that the individual is unable to obtain the security plan or implementing procedures.

(vii) When not in use, the licensee shall store its security plan and implementing procedures in a manner to prevent unauthorized access. Information stored in nonremovable electronic form shall be password protected.

(viii) The licensee shall make, maintain, and retain as a record for inspection by the agency in accordance with subsection (mm) of this section:

(I) a copy of the information protection procedures; and

(II) the list of individuals approved for access to the security plan or implementing procedures.

(11) LLEA coordination.

(A) A licensee subject to paragraphs (9) and (10), this paragraph, and paragraphs (12) - (17) of this subsection shall coordinate, to the extent practicable, with an LLEA for responding to threats

to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

(i) a description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with paragraphs (9) and (10), this paragraph, and paragraphs (12) - (17) of this subsection; and

(ii) a notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.

(B) The licensee shall notify the agency within 3 business days if:

(i) the LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(ii) the LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

(C) The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for inspection by the agency in accordance with subsection (mm) of this section.

(D) The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

(12) Security zones.

(A) Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee established security zones. Security zones may be permanent or temporary.

(B) Temporary security zones shall be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

(C) Security zones must, at a minimum, allow unescorted access only to approved individuals through:

(i) isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or

(ii) direct control of the security zone by approved individuals at all times; or

(iii) a combination of continuous physical barriers and direct control.

(D) For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

(E) Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

(13) Monitoring, detection and assessment.

(A) Monitoring and detection.

(i) Licensees shall:

(I) establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones;

(II) provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source; or

(III) provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(ii) Monitoring and detection must be performed by:

(I) a monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility;

(II) electronic devices for intrusion detection alarms that will alert nearby facility personnel;

(III) a monitored video surveillance system;

(IV) direct visual surveillance by approved individuals located within the security zone; or

(V) direct visual surveillance by a licensee designated individual located outside the security zone.

(iii) A licensee subject to paragraphs (9) - (12), this paragraph, and paragraphs (14) - (17) of this subsection shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

(I) for category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

(-a-) electronic sensors linked to an alarm;

(-b-) continuous monitored video surveillance; or

(-c-) direct visual surveillance; and

(II) for category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

(B) Assessment. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

(C) Personnel communications and data transmission. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:

(i) maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

(ii) provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

(D) Response. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

(14) Maintenance and testing.

(A) Each licensee subject to paragraphs (9) - (13), this paragraph, and paragraphs (15) - (17) of this subsection shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this subsection must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no suggested manufacturer's suggested frequency, the testing must be performed at least annually, not to exceed 12 months.

(B) The licensee shall maintain records on the maintenance and testing activities for inspection by the agency in accordance with subsection (mm) of this section.

(15) Requirements for mobile devices. Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material shall:

(A) have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

(B) for devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

(16) Security program review.

(A) Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of paragraphs (9) - (15), this paragraph, and paragraph (17) of this subsection, and that comprehensive actions are taken to correct any noncompliance that is identified. The review shall include the radioactive material security program content and implementation. Each licensee shall review the security program content and implementation at least every 12 months.

(B) The results of the review, along with any recommendations, must be documented.

(i) Each review report must:

(I) identify conditions that are adverse to the proper performance of the security program,

(II) identify the cause of the condition(s); and

(III) when applicable, recommend corrective actions, and identify and document any corrective actions taken.

(ii) The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of

the condition, including reassessment of the deficient areas where indicated.

(C) The licensee shall make, maintain, and retain the documentation of the review required under subparagraph (B) of this paragraph for inspection by the agency in accordance with subsection (mm) of this section.

(17) Reporting of events.

(A) The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the agency at (512) 458-7460. In no case shall the notification to the agency be later than 4 hours after the discovery of any attempted or actual theft, sabotage, or diversion.

(B) The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than 4 hours after notifying the LLEA, the licensee shall notify the agency at (512) 458-7460.

(C) Each initial telephonic notification required by subparagraphs (A) and (B) of this paragraph must be followed within a period of 30 days by a written report submitted to the agency. The report must include sufficient information for agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

(18) Additional requirements for transfer of category 1 and category 2 quantities of radioactive material. A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the agency, the NRC, or any agreement state shall meet the license verification requirements listed below instead of those listed in subsection (cc)(4) of this section.

(A) Any licensee transferring category 1 quantities of radioactive material to a licensee of the agency, the NRC, or any agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(B) Any licensee transferring category 2 quantities of radioactive material to a licensee of the agency, the NRC, or any agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(C) In an emergency where the licensee cannot reach the license issuing authority and the license verification system is non-functional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred.

(i) The certification must include:

- (I) the license number;
- (II) the current revision number;
- (III) the issuing authority;
- (IV) the expiration date; and
- (V) for a category 1 shipment, the authorized address.

(ii) The licensee shall keep a copy of the certification.

(iii) The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

(D) The transferor shall keep a copy of the verification documentation required under this paragraph as a record for inspection by the agency in accordance with subsection (mm) of this section.

(19) Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit. The shipping licensee shall be responsible for meeting the requirements of paragraph (18), this paragraph, and paragraphs (20) - (23) of this subsection unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under paragraph (18), this paragraph, and paragraphs (20) - (23) of this subsection.

(20) Preplanning and coordination of shipment of category 1 and category 2 quantities of radioactive material.

(A) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(i) preplan and coordinate shipment arrival and departure times with the receiving licensee;

(ii) preplan and coordinate shipment information with the governor or the governor's designee of any state through which the shipment will pass to:

(I) discuss the state's intention to provide law enforcement escorts; and

(II) identify safe havens; and

(iii) document the preplanning and coordination activities.

(B) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

(C) Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

(D) Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to subparagraph (B) of this paragraph, shall promptly notify the receiving licensee of the new no-later-than arrival time.

(E) The licensee shall make, maintain, and retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for inspection by the agency in accordance with subsection (mm) of this section.

(21) Advance notification of shipment of category 1 quantities of radioactive material. As specified in subparagraphs (A) and (B) of this paragraph, for shipments initially made by an agreement state licensee, each licensee shall provide advance notification to the Texas Department of Public Safety and the governor of a state, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the state, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

(A) Procedures for submitting advance notification.

(i) The notification must be made to the Texas Department of Public Safety and to the office of each appropriate governor or governor's designee.

(I) The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the NRC's Web site at <http://nrc-stp.ornl.gov/special/designee.pdf>. A list of agreement state advance notification contact information is also available upon request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(II) Notifications to the Texas Department of Public Safety must be to the Director, Texas Department of Public Safety, Office of Homeland Security, P.O. Box 4087, Austin, Texas 78773 or by fax to (512) 424-5708.

(ii) A notification delivered by mail must be post-marked at least 7 days before transport of the shipment commences at the shipping facility.

(iii) A notification delivered by any means other than mail must reach the Texas Department of Public Safety at least 4 days before the transport of the shipment commences; and

(iv) A notification delivered by any means other than mail must reach the office of the governor or the governor's designee at least 4 days before transport of a shipment within or through the state.

(B) Information to be furnished in advance notification of shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

(i) the name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

(ii) the license numbers of the shipper and receiver;

(iii) a description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(iv) the point of origin of the shipment and the estimated time and date that shipment will commence;

(v) the estimated time and date that the shipment is expected to enter each state along the route;

(vi) the estimated time and date of arrival of the shipment at the destination; and

(vii) a point of contact, with a telephone number, for current shipment information.

(C) Revision notice.

(i) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the state or the governor's designee and to the Director, Texas Department of Public Safety, Office of Homeland Security, P.O. Box 4087, Austin, Texas 78773 or by fax to (512) 424-5708.

(ii) A licensee shall provide notice as follows of any changes to the information provided in accordance with subparagraphs (B) and (C)(i) of this paragraph.

(I) Promptly notify the governor of the state or the governor's designee.

(II) Immediately notify the Director, Texas Department of Public Safety, Office of Homeland Security, P.O. Box 4087, Austin, Texas 78773 or by fax to (512) 424-5708.

(D) Cancellation notice.

(i) Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to:

(I) the governor of each state or to the governor's designee previously notified; and

(II) the Director, Texas Department of Public Safety, Office of Homeland Security, P.O. Box 4087, Austin, Texas 78773 or by fax to (512) 424-5708.

(ii) The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible.

(iii) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(E) Records. The licensee shall make, maintain, and retain a copy of the advance notification and any revision and cancellation notices as a record for inspection by the agency in accordance with subsection (mm) of this section.

(F) Protection of information. State officials, state employees, and other individuals, whether or not licensees of the agency, the NRC, or any agreement state, who receive schedule information of the kind specified in subparagraph (B) of this paragraph shall protect that information against unauthorized disclosure as specified in paragraph (10)(D) of this subsection.

(22) Requirements for physical protection of category 1 or category 2 quantities of radioactive material during shipment.

(A) Shipments by road.

(i) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(I) ensure that movement control centers are established that maintain position information from a remote location. These control centers shall monitor shipments 24 hours a day, 7 days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies;

(II) ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication;

(III) ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center shall provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route;

(IV) provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver; and

(V) develop written normal and contingency procedures to address:

- (-a-) notifications to the communication center and law enforcement agencies;
- (-b-) communication protocols, which must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;
- (-c-) loss of communications; and
- (-d-) responses to an actual or attempted theft or diversion of a shipment.

(ii) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(iii) Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(iv) Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(I) use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(II) use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(III) use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(B) Shipments by rail.

(i) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(I) ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications cen-

ter. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route; and

(II) ensure that periodic reports to the communications center are made at preset intervals.

(ii) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(I) use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(II) use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(III) use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(C) Investigations.

(i) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing.

(ii) Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

(23) Reporting of events.

(A) The shipping licensee shall notify the appropriate LLEA and shall notify the agency at (512) 458-7460 within one hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by paragraph (22)(C) of this subsection, the shipping licensee will provide agreed upon updates to the agency on the status of the investigation.

(B) The shipping licensee shall notify the agency at (512) 458-7460 within 4 hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the agency.

(C) The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the agency at (512) 458-7460 upon discovery of any actual or attempted theft or diversion of a shipment,

or any suspicious activity related to the shipment of category 1 radioactive material.

(D) The shipping licensee shall notify the agency at (512) 458-7460 as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.

(E) The shipping licensee shall notify the agency at (512) 458-7460 and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

(F) The shipping licensee shall notify the agency at (512) 458-7460 as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

(G) The initial telephonic notification required by subparagraphs (A) - (D) of this paragraph must be followed within a period of 30 days by a written report submitted to the agency. A written report is not required for notifications on suspicious activities required by subparagraphs (C) and (D) of this paragraph. In addition, the licensee shall provide one copy of the written report addressed to the Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The report must set forth the following information:

(i) a description of the licensed material involved, including kind, quantity, and chemical and physical form;

(ii) a description of the circumstances under which the loss or theft occurred;

(iii) a statement of disposition, or probable disposition, of the licensed material involved;

(iv) actions that have been taken, or will be taken, to recover the material; and

(v) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(H) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(24) Form of records. Each record required by this subsection shall be legible throughout the retention period specified in the agency's rules. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(25) Record retention. All records/documents referenced in this subsection shall be made and maintained by the licensee for inspection by the agency in accordance with subsection (mm) of this section. If a retention period is not otherwise specified, these records must be retained until the agency terminates the facility's license. All records related to this subsection may be destroyed upon agency termination of the facility license.

(jj) Appendices.

(1) Subjects to be included in training courses:

(A) fundamentals of radiation safety:

(i) characteristics of radiation;

(ii) units of radiation dose (rem) and activity of radioactivity (curie);

(iii) significance of radiation dose;

(I) radiation protection standards; and

(II) biological effects of radiation;

(iv) levels of radiation from sources of radiation;

(v) methods of controlling radiation dose;

(I) time;

(II) distance; and

(III) shielding;

(vi) radiation safety practices, including prevention of contamination and methods of decontamination; and

(vii) discussion of internal exposure pathways;

(B) radiation detection instrumentation to be used:

(i) radiation survey instruments:

(I) operation;

(II) calibration; and

(III) limitations;

(ii) survey techniques; and

(iii) individual monitoring devices;

(C) equipment to be used:

(i) handling equipment and remote handling tools;

(ii) sources of radiation;

(iii) storage, control, disposal, and transport of equipment and sources of radiation;

(iv) operation and control of equipment; and

(v) maintenance of equipment;

(D) the requirements of pertinent federal and state regulations;

(E) the licensee's written operating, safety, and emergency procedures; and

(F) the licensee's record keeping procedures.

(2) Isotope quantities (for use in subsection (gg) of this section).

Figure: 25 TAC §289.252(jj)(2)

(3) Criteria relating to use of financial tests and parent company guarantees for providing reasonable assurance of funds for decommissioning.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This paragraph establishes criteria for passing the financial test and for obtaining the parent company guarantee.

(B) Financial test.

(i) To pass the financial test, the parent company shall meet the criteria of either subclause (I) or (II) of this clause.

(I) The parent company shall have:

(-a-) two of the following three ratios:

(-1-) a ratio of total liabilities to net worth less than 2.0;

(-2-) a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and

(-3-) a ratio of current assets to current liabilities greater than 1.5;

(-b-) net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used);

(-c-) tangible net worth of at least \$10 million; and

(-d-) assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used.)

(II) The parent company shall have:

(-a-) a current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's;

(-b-) tangible net worth each at least six times the current decommissioning cost estimate for the total of all facilities or parts thereof (or prescribed amount if a certification is used);

(-c-) tangible net worth of at least \$10 million; and

(-d-) assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if certification is used).

(ii) The parent company's independent certified public accountant shall have compared the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters coming to the auditor's attention that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(iii) After the initial financial test, the parent company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(iv) If the parent company no longer meets the requirements of clause (i) of this subparagraph, the licensee shall send notice to the agency of intent to establish alternate financial assurance as specified in the agency's regulations. The notice shall be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

(C) Parent company guarantee. The terms of a parent company guarantee that an applicant or licensee obtains shall provide that:

(i) the parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail

to the licensee and the agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the agency, as evidenced by the return receipts;

(ii) if the licensee fails to provide alternate financial assurance as specified in the agency's rules within 90 days after receipt by the licensee and the agency of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee;

(iii) the parent company guarantee and financial test provisions shall remain in effect until the agency has terminated the license; and

(iv) if a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the agency. An acceptable trustee includes an appropriate state or federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

(4) Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes a financial test of subparagraph (B) of this paragraph. Subparagraph (B) of this paragraph establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self guarantee.

(B) Financial test.

(i) To pass the financial test, a company shall meet all of the following criteria:

(I) tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used for all decommissioning activities for which the company is responsible as self guaranteeing licensee and as parent-guarantor);

(II) assets located in the United States amounting to at least 90% of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor); and

(III) a current rating for its most recent bond issuance of AAA, AA, A as issued by Standard and Poor's, or Aaa, Aa, A as issued by Moody's.

(ii) To pass the financial test, a company shall meet all of the following additional criteria:

(I) the company shall have at least one class of equity securities registered under the Securities Exchange Act of 1934;

(II) the company's independent certified public accountant shall have compared the data used by the company in the financial test that is derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters coming to the auditor's attention that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test; and

(III) after the initial financial test, the company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(iii) If the licensee no longer meets the criteria of clause (i) of this subparagraph, the licensee shall send immediate notice to the agency of its intent to establish alternate financial assurance as specified in the agency's rules within 120 days of such notice.

(C) Company self guarantee. The terms of a self guarantee that an applicant or licensee furnishes shall provide that:

(i) the company guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the agency, as evidenced by the return receipt;

(ii) the licensee shall provide alternate financial assurance as specified in the agency's rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee;

(iii) the guarantee and financial test provisions shall remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee;

(iv) the licensee will promptly forward to the agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission in accordance with the requirements of the Securities and Exchange Act of 1934, §13;

(v) if, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee will provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the criteria of subparagraph (B)(i) of this paragraph; and

(vi) the applicant or licensee shall provide to the agency a written guarantee (a written commitment by a corporate officer) that states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(5) Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning by commercial companies that have no outstanding rated bonds.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of subparagraph (B) of this paragraph. The terms of the self-guarantee are in subparagraph (C) of this paragraph. This paragraph establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

(B) Financial test.

(i) To pass the financial test a company shall meet the following criteria:

(I) tangible net worth greater than \$10 million, or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is

greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor;

(II) assets located in the United States amounting to at least 90% of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor; and

(III) a ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

(ii) In addition, to pass the financial test, a company shall meet all of the following requirements:

(I) the company's independent certified public accountant shall have compared the data used by the company in the financial test, that is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in the financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test;

(II) after the initial financial test, the company shall repeat passage of the test within 90 days after the close of each succeeding fiscal year; and

(III) if the licensee no longer meets the requirements of subparagraph (B)(i) of this paragraph, the licensee shall send notice to the agency of intent to establish alternative financial assurance as specified in the agency's rules. The notice shall be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee shall provide alternative financial assurance within 120 days after the end of such fiscal year.

(C) Company self-guarantee. The terms of a self-guarantee that an applicant or licensee furnishes shall provide the following.

(i) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

(ii) The licensee shall provide alternative financial assurance as specified in the agency rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

(iii) The guarantee and financial test provisions shall remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

(iv) The applicant or licensee shall provide to the agency a written guarantee (a written commitment by a corporate officer) that states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(6) Criteria relating to use of financial tests and self-guarantees for providing reasonable assurance of funds for decommissioning by nonprofit entities, such as colleges, universities, and nonprofit hospitals.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning

based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of subparagraph (B) of this paragraph. The terms of the self-guarantee are in subparagraph (C) of this paragraph. This paragraph establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee

(B) Financial test.

(i) To pass the financial test, a college or university shall meet the criteria of subclause (I) or (II) of this clause. The college or university shall meet one of the following:

(I) for applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's or Aaa, Aa, or A as issued by Moody's; or

(II) for applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least \$50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

(ii) To pass the financial test, a hospital shall meet the criteria in subclause (I) or (II) of this clause. The hospital shall meet one of the following:

(I) for applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's or Aaa, Aa, or A as issued by Moody's; or

(II) for applicants or licensees that do not issue bonds, all the following tests shall be met:

(-a-) (total revenues less total expenditures) divided by total revenues shall be equal to or greater than 0.04;

(-b-) long term debt divided by net fixed assets shall be less than or equal to 0.67;

(-c-) (current assets and depreciation fund) divided by current liabilities shall be greater than or equal to 2.55; and

(-d-) operating revenues shall be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

(iii) In addition, to pass the financial test, a licensee shall meet all the following requirements:

(I) the licensee's independent certified public accountant shall have compared the data used by the licensee in the financial test that is required to be derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in the financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test; and

(II) after the initial financial test, the licensee shall repeat passage of the test within 90 days after the close of each succeeding fiscal year;

(III) if the licensee no longer meets the requirements of subparagraph (A) of this paragraph, the licensee shall send notice to the agency of its intent to establish alternative financial assurance as specified in the agency's rules. The notice shall be sent by

certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

(C) Self-guarantee. The terms of a self-guarantee that an applicant or licensee furnishes shall provide the following:

(i) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the agency. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

(ii) The licensee shall provide alternative financial assurance as specified in the agency's regulations within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

(iii) The guarantee and financial test provisions shall remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

(iv) The applicant or licensee shall provide to the agency a written guarantee (a written commitment by a corporate officer or officer of the institution) that states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(v) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of the fact to the agency within 20 days after publication of the change by the rating service.

(7) Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release. The following table contains quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

Figure: 25 TAC §289.252(jj)(7)

(8) Requirements for demonstrating financial qualifications.

(A) If an applicant or licensee is not required to submit financial assurance in accordance with subsection (gg) of this section, that applicant or licensee shall demonstrate financial qualification by submitting attestation that the applicant or licensee is financially qualified to conduct the activity requested for licensure, including any required decontamination, decommissioning, reclamation, and disposal before the agency issues a license.

(B) If an applicant or licensee is required to submit financial assurance in accordance with subsection (gg) of this section, that applicant or licensee shall:

(i) submit one of the following:

(I) the bonding company report or equivalent (from which information can be obtained to calculate a ratio in clause (ii) of this subparagraph) that was used to obtain the financial assurance instrument used to meet the financial assurance requirement specified in subsection (gg) of this section. However, if the applicant or licensee posted collateral to obtain the financial instrument used to meet the requirement for financial assurance specified in subsection (gg) of this section, the applicant or licensee shall demonstrate financial

qualification by one of the methods specified in subclause (II) or (III) of this clause;

(II) Securities and Exchange Commission documentation (from which information can be obtained to calculate a ratio as described in clause (ii) of this subparagraph, if the applicant or licensee is a publicly-held company); or

(III) a self-test (for example, an annual audit report certifying a company's assets and liabilities and resulting ratio as described in clause (ii) of this subparagraph or, in the case of a new company, a business plan specifying expected expenses versus capitalization and anticipated revenues); and

(ii) declare its Standard Industry Classification (SIC) code. Several companies publish lists, on an annual basis, of acceptable assets-to liabilities (assets divided by liabilities) ratio ranges for each type of SIC code. If an applicant or licensee submits documentation of its current assets and current liabilities or, in the case of a new company, a business plan specifying expected expenses versus capitalization and anticipated revenues, and the resulting ratio falls within an acceptable range as published by generally recognized companies (for example, Almanac of Business and Industrial Financial Ratios, Industry NORM and Key Business Ratios, Dun & Bradstreet Industry publications, and Manufacturing USA: Industry Analyses, Statistics, and Leading Companies), the agency will consider that applicant or licensee financially qualified to conduct the requested or licensed activity.

(C) If the applicant or licensee is a state or local government entity, a statement of such will suffice as demonstration that the government entity is financially qualified to conduct the requested or licensed activities.

(D) The agency will consider other types of documentation if that documentation provides an equivalent measure of assurance of the applicant's or licensee's financial qualifications as found in subparagraphs (A) and (B) of this paragraph.

(9) Category 1 and category 2 radioactive materials. Licensees shall use Figure: 25 TAC §289.252(jj)(9) to determine whether a quantity of radioactive material constitutes a Category 1 or Category 2 quantity of radioactive material. Figure: 25 TAC §289.252(jj)(9)

(kk) Requirements for the issuance of specific licenses for a medical facility or educational institution to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium.

(1) A license application will be approved if the agency determines that an application from a medical facility or educational institution to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use in accordance with §289.256 of this title includes:

(A) a request for authorization for the production of PET radionuclides or evidence of an existing license issued in accordance with this section, the NRC, or another agreement states requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides;

(B) evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in subsection (r)(1)(A) of this section;

(C) identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in subsection (r)(3)(B) of this section; and

(D) information identified in subsection (r)(1)(B) of this section on the PET drugs to be noncommercially transferred to members of its consortium.

(2) Authorization in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

(3) Each licensee authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(A) satisfy the labeling requirements in subsection (r)(1)(C) of this section for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and

(B) possess and use instrumentation meeting the requirements of §289.202(p)(3)(D) of this title to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in subsection (r)(2) of this section.

(4) A licensee that is a pharmacy authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(A) an authorized nuclear pharmacist that meets the requirements in subsection (r)(3)(B) of this section; or

(B) an individual under the supervision of an authorized nuclear pharmacist as specified in §289.256(s) of this title.

(5) A pharmacy, authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of subsection (r)(3)(E) of this section.

(II) Specific licenses for installation, repair, or maintenance of devices containing sealed sources of radioactive material.

(1) In addition to the requirements in subsection (e) of this section, a specific license authorizing persons to perform installation, repair, or maintenance of devices containing sealed source(s) including source exchanges will be issued if the agency approves the information submitted by the applicant.

(2) Each installation, repair, or maintenance activity shall be documented and a record maintained for inspection by the agency in accordance with subsection (mm) of this section. The record shall include the date, description of the service, initial survey results, and name(s) of the individual(s) who performed the work.

(3) Installation, repair, maintenance, or source exchange activities shall be performed by a specifically licensed person unless otherwise authorized in accordance with subsection (v) of this section.

(mm) Records/documents retention. Each licensee shall make, maintain, and retain at each authorized use site and for the time period set forth in the table, the records/documents described in the following table and in the referenced rule provision, and shall make them available to the agency for inspection, upon reasonable notice. Figure: 25 TAC §289.252(mm)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Lisa Hernandez

General Counsel

Department of State Health Services

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For further information, please call: (512) 776-6972



TITLE 28. INSURANCE

PART 1. TEXAS DEPARTMENT OF INSURANCE

CHAPTER 5. PROPERTY AND CASUALTY INSURANCE

The Texas Department of Insurance adopts new 28 TAC Chapter 5, Subchapter M, Division 5, §5.9323 and new Subchapter Q, Division 1, §5.9700 with changes to the proposed text published in the August 28, 2015, issue of the *Texas Register* (40 TexReg 5445). The new sections are necessary to implement Insurance Code §2301.056, added by SB 112, 83rd Legislature, Regular Session (2013). On November 5, 2015, TDI held a public hearing on the proposal. In response to comments, TDI made a number of changes to the text, which are detailed below.

REASONED JUSTIFICATION. For residential property insurance policy forms, Insurance Code §2301.056 requires that:

1. the declarations page state the exact dollar amount of each deductible under the policy; and
2. the declarations page or a page separate from the declarations page:
 - a. list and identify each type of deductible under the residential property policy; and
 - b. identify or disclose any policy provision or endorsement that may cause the exact dollar amount of a deductible to change.

The new sections clarify that for residential property policy insurance forms:

1. insurers must file declarations pages with TDI for review and approval under Insurance Code §2301.006;
2. insurers must file renewal and amended declarations pages, and renewal certificates used as declarations pages;
3. no deductibles are exempt;
4. insurers must issue declarations pages at renewal if a deductible changes;
5. if using a separate disclosure page under §2301.056(c), that page must follow immediately after the declarations page; and
6. insurers that choose to provide separate disclosure pages must include them each time they provide a declarations page or renewal certificate to a policyholder.

Before SB 112, no statute specifically required insurers to file declarations pages, although some insurers did so. With the enactment of SB 112, Insurance Code §2301.056 provides specific requirements for declarations pages, and TDI must now review them for compliance.

TDI is implementing Insurance Code §2301.056 in two separate rule sections. Section 5.9323 contains the filing requirements and will be part of the Filings Made Easy rules. Section 5.9700 contains the substantive requirements related to disclosing deductibles. These sections are effective September 1, 2016.

This order summarizes the comments TDI received on the proposed rules. In response to comments on the published proposal, TDI has adopted changes to the proposed text to improve clarity. The changes do not introduce new subject matter, create additional costs, or affect persons other than those previously on notice from the proposal.

Section 5.9323. Residential Property Declarations Page Forms. To ensure all declarations page forms comply with §2301.056, new §5.9323 specifies that insurers must file residential property insurance policy declarations page forms, including forms for renewal declarations pages, renewal certificates, amended declarations pages, and separate disclosure pages. Section 5.9323(b) specifies that insurers must file forms completed with sample - not actual - policyholder information, so TDI can verify that insurers will list the required deductible information.

TDI made changes to the proposed text in response to comments. These changes do not affect persons not previously on notice, nor do they raise new issues. The section heading of adopted §5.9323 is changed to "Residential Property Declarations Page Forms," and subsections (a) and (b) also now include the word "forms" to clarify that insurers must file sample declarations page forms rather than actual declarations pages. TDI added the phrase "not actual" to adopted subsection (b), to reiterate that insurers need only file sample policyholder information, rather than actual policyholder information. These changes clarify the filing requirements, and do not affect persons not previously on notice, nor do they raise new issues.

Section 5.9700. Residential Property Declarations Pages and Deductible Disclosures. For ease of use, new §5.9700 includes the statutory requirements for disclosing deductibles. Insurance Code §2301.056 does not exempt any deductibles, so §5.9700(a) specifies that deductibles include each type of deductible in the policy, which includes applicable endorsements. In response to comments, TDI removed the word "subdeductible" from §5.9700(a) as proposed, and added an example of how an insurer can identify a deductible.

Section 5.9700(b) reiterates the requirement in Insurance Code §2301.056(b) that the declarations page or a separate disclosure page identify or include a written disclosure that clearly identifies the applicable policy provision or endorsement if a residential property insurance policy or endorsement contains a provision that may cause the exact dollar amount of a deductible under the policy to change. In response to comments, TDI added an example of how an insurer can identify the applicable policy provision or endorsement.

Insurance Code §2301.056 also allows insurers to provide the required disclosures on a page separate from the declarations page. To ensure that policyholders can easily find the disclosures, §5.9700(c) requires that the separate disclosure page follow immediately after the declarations page.

Responding to comments, TDI revised §5.9700 as proposed to insert a new subsection (d) to clarify that a declarations page and a separate disclosure page may each consist of more than one page.

To ensure policyholders have the most current information, if a deductible changes on the declarations page or a separate disclosure page, adopted §5.9700(e), which was proposed as subsection (d), requires insurers, at renewal, to issue a declarations page or renewal certificate. In response to comments, TDI removed the word "updated" from the proposed text to avoid confusion.

Section 5.9700(f), which was proposed as subsection (e), requires that insurers and agents include the separate disclosure page each time they provide a declarations page or renewal certificate to a policyholder, to further ensure that the policyholder has access to the most current deductible information. In response to comments, TDI specified that use of a separate disclosure page is at the option of the insurer or agent. Insurers that choose to provide separate disclosure pages must include the disclosure pages with the declarations page each time they provide a declarations page or renewal certificate to a policyholder.

None of the changes to §5.9700 as adopted affect persons not previously on notice, nor do they raise new issues.

SUMMARY OF COMMENTS AND AGENCY RESPONSE.

General Comments

Comment: Two commenters requested a public hearing.

Agency Response: TDI held a public hearing on November 5, 2015, in accordance with Government Code §2001.029.

Comment: A commenter asked TDI to limit the scope of the rules to personal lines residential property.

Agency Response: Both §5.9323 and §5.9700 specifically refer to residential property insurance policy declarations page forms, reflecting the requirement in Insurance Code §2301.056. Nothing in the rule or statute suggests that the scope extends beyond residential property.

Comment: A commenter asked TDI to extend the effective date 12 months, so insurers may implement necessary changes to comply with the new rules.

Agency Response: Section 2301.056 was effective September 1, 2013, and insurers should already be complying with declaration page requirements. Nonetheless, to allow insurers time to adapt to filing forms with sample policyholder information, TDI will extend the effective date six months. The adopted rules will be effective September 1, 2016.

Comment: A commenter stated that the Legislature did not intend to require prior approval of declarations pages when passing SB 112; but instead, the Legislature intended to simply require clear descriptions of how deductibles are calculated, and to provide the dollar amounts rather than percentage deductibles. The commenter expresses concern that prior approval of declarations pages is an additional regulatory burden.

Agency Response: Insurance Code §2301.056 requires residential insurance policy forms to include declarations pages. Insurance Code §2301.006 requires insurers to file policy forms. Therefore, insurers must file declarations pages as part of residential property insurance policy forms.

Comment: A commenter stated that the cost estimate should be higher than stated in the proposal if insurers are required to make multiple new filings of renewal declarations pages and required separate disclosure pages.

Agency Response: Insurers are not required to file declarations or disclosure pages sent to actual policyholders. Rather, they are only required to file the forms, completed with sample policyholder information. TDI clarified this by adding the word "forms" to the filing requirements in §5.9323. TDI finds that the cost estimate as proposed is accurate.

Comments on §5.9323

Comment: A commenter asked that TDI delete the word "disclosure" from the section heading, and instead substitute the word "page" because "disclosure" is confusing.

Agency Response: TDI changed the section heading as adopted. As adopted, the section heading for §5.9323 is "Residential Property Declarations Page Forms."

Comment: A commenter expressed concern that the rule would require insurers to file new policy forms for each policy issued and refile every time there is any change in the dollar amount of a deductible or at renewal for each individual policyholder. The commenter suggested providing brackets and adding language similar to the variable material in life and health filings.

Agency Response: TDI revised §5.9323 as proposed to clarify that insurers are only required to file forms and not issued policies, disclosures, or declarations pages. If the insurer's declarations page form changes, the insurer must file the form, complete with sample information, as opposed to each unique policyholder declarations page. TDI revised subsection (b) as proposed to emphasize that insurers must not file any actual policyholder information, including policy numbers or other personal identifying information.

Comments on §5.9700

Comment: A commenter suggested TDI define "lists" and "identifies" as described in proposed §5.9700 or provide guidance as to what is acceptable. The commenter asks for clarification on what constitutes a sufficient listing or identification of a deductible, to help insurers generate compliant declarations pages.

Agency Response: TDI revised §5.9700(a) and (b) to add clarifying examples: "To identify a deductible, the insurer must provide a brief description, such as: 'Wind and Hail,' 'Earthquake,' or 'Jewelry,'" and "To identify the applicable policy provision or endorsement, the insurer must provide a brief description and reference, such as, 'Inflation Adjustments: See page 1, Section A.2.a.'"

Comment: A commenter asks that TDI allow insurers to combine the declarations page and the separate disclosure into one document and affirmatively state insurers have the option to issue declarations pages that consist of more than one page to include all information required by the statute.

Agency Response: TDI clarified §5.9700 by adding new subsection (d) to provide that declarations pages and separate disclosures pages may each consist of more than one page. If an insurer chooses to use separate disclosures pages, the pages must immediately follow the declarations pages.

Comment: A commenter states the term "subdeductible" is unclear.

Agency Response: The statute requires that a declarations page list and identify each type of deductible. This does not exclude any deductibles, so TDI removed "subdeductible" in subsection (a) to avoid confusion.

Comment: A commenter states that in proposed §5.9700(d), the word "updated" and the alternative language at the end of the sentence is ambiguous and confusing and may create compliance issues, depending on how future TDI employees interpret the language.

Agency Response: As adopted, TDI removed the word "updated" and inserted additional text to the subsection, which was adopted as subsection (e), to clarify that if a deductible changes, insurers must issue a declarations page or renewal certificate at renewal.

Comment: A commenter suggests that proposed §5.9700(e) appears to require a separate disclosure page for each policy and asks for its removal.

Agency Response: TDI revised part of proposed §5.9700(e), adopted as subsection (f), clarifying that only insurers that provide separate disclosure pages must include them when they provide declarations pages or renewal certificates to policyholders.

NAMES OF THOSE COMMENTING FOR AND AGAINST THE PROPOSAL.

For with changes: National Association of Mutual Insurance Companies, American Insurance Association, the Insurance Council of Texas, and the Texas Coalition of Affordable Insurance Solutions.

Against: Property Casualty Insurers Association of America.

SUBCHAPTER M. FILING REQUIREMENTS DIVISION 5. FILINGS MADE EASY - REQUIREMENTS FOR PROPERTY AND CASUALTY POLICY FORM, ENDORSEMENT, AND MANUAL RULE FILINGS

28 TAC §5.9323

STATUTORY AUTHORITY. Section 5.9323 is adopted under Insurance Code §§2301.056, 2301.055, and 36.001. Section 2301.056 requires that declarations pages for residential property insurance policy forms fully disclose all deductibles. Section 2301.055 provides that the commissioner may adopt reasonable and necessary rules to implement Chapter 2301, Subchapter B. Section 36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

§5.9323. Residential Property Declarations Page Forms.

(a) Insurers must file residential property insurance policy declarations page forms for approval under §5.9320 of this title (relating to Required Information for the Preparation and Submission of Policy Form, Endorsement, and Manual Rule (Other than Rating Manual) Filings). Declarations pages include renewal declarations pages, renewal certificates, amended declarations pages, and separate disclosure pages allowed under §5.9700 of this title (relating to Residential Property Declarations Pages and Deductible Disclosures).

(b) Filed declarations page forms must be completed with sample - not actual - policyholder information sufficient to demon-

strate how the insurer will comply with this rule and Insurance Code §2301.056.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Norma Garcia

General Counsel

Texas Department of Insurance

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For further information, please call: (512) 676-6584

SUBCHAPTER Q. GENERAL PROPERTY AND CASUALTY RULES DIVISION 1. RESIDENTIAL PROPERTY

28 TAC §5.9700

STATUTORY AUTHORITY. Section 5.9700 is adopted under Insurance Code §§2301.056, 2301.055, and 36.001. Section 2301.056 requires that declarations pages for residential property insurance policy forms fully disclose all deductibles. Section 2301.055 provides that the commissioner may adopt reasonable and necessary rules to implement Chapter 2301, Subchapter B. Section 36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

§5.9700. Residential Property Declarations Pages and Deductible Disclosures.

(a) All residential property insurance policy declarations pages must list and identify each type of deductible in the policy, including applicable endorsements, and state the exact dollar amount of each deductible. To identify a deductible, the insurer must provide a brief description, such as "Wind and Hail," "Earthquake," or "Jewelry."

(b) If a residential property insurance policy or endorsement contains a provision that may cause the exact dollar amount of a deductible under the policy to change, the declarations page or a separate disclosure page must identify or include a written disclosure that clearly identifies the applicable policy provision or endorsement. The policy provision or endorsement must explain how any change in the applicable deductible amount is determined. To identify the applicable policy provision or endorsement, the insurer must provide a brief description and reference, such as "Inflation Adjustments: See page 1, Section A.2.a."

(c) Insurers may provide disclosures under this section on a separate disclosure page. The separate disclosure page must follow immediately after the declarations page.

(d) A declarations page and a separate disclosure page may each consist of more than one page.

(e) Insurers must issue a declarations page at renewal if the dollar amount of a deductible changes on the declarations page or separate disclosure page. Alternatively, insurers may issue a renewal cer-

tificate that meets the requirements of this rule and Insurance Code §2301.056.

(f) Insurers and agents that provide separate disclosure pages must include them with the declarations page each time they provide a declarations page, as defined in §5.9323(a), to a policyholder.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Norma Garcia

General Counsel

Texas Department of Insurance

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For further information, please call: (512) 676-6584



TITLE 40. SOCIAL SERVICES AND ASSISTANCE

PART 19. DEPARTMENT OF FAMILY AND PROTECTIVE SERVICES

CHAPTER 745. LICENSING

The Health and Human Services Commission adopts, on behalf of the Department of Family and Protective Services (DFPS), the repeal of the current version of Subchapter O, Independent Court-Ordered Social Studies, consisting of §§745.9060, 745.9061, 745.9063, 745.9065, 745.9067, 745.9068, 745.9069 - 745.9071, 745.9073, 745.9075, 745.9077, 745.9079, 745.9081, 745.9083, 745.9085, 745.9087, 745.9089, 745.9090, 745.9091 - 745.9097, and 745.9100; and new Subchapter O, Independent Court-Ordered Adoption Evaluations, consisting of §§745.9041, 745.9043, 745.9045, 745.9047, 745.9049, 745.9051, 745.9053, 745.9055, 745.9057, 745.9059, 745.9061, 745.9063, 745.9065, 745.9067, 745.9069, 745.9071, 745.9073, 745.9075, 745.9077, 745.9079, 745.9081, 745.9083, 745.9085, 745.9087, 745.9089, 745.9091, 745.9093, 745.9095, 745.9097, and 745.9098, without changes to the proposed text published in the November 13, 2015, issue of the *Texas Register* (40 TexReg 7999).

The justification of the revision is to implement portions of House Bill (HB) 1449 that was passed by the 84th Texas Legislature in 2015. The changes to the law overhaul the current statutes regarding "social studies" in Chapter 107 of the Texas Family Code (TFC). The new statutory language divides "social studies" into two sections: Child Custody Evaluations and Adoption Evaluations. TFC, Chapter 107, Subchapter E, Adoption Evaluations, requires DFPS to establish minimum requirements for what is now called "pre-placement and post-placement portions of an adoption evaluation." No rules are mandated for Child Custody Evaluations.

These rules do not apply to adoption evaluations conducted by DFPS, contractors of DFPS, or child placing agencies (CPAs), which are governed by other laws and standards. These rules will only apply in independent adoption situations where a court orders an adoption evaluator to conduct an adoption evaluation.

Child Care Licensing (CCL) has no authority over or enforcement powers regarding the adoption evaluators. CCL's only role is to propose and adopt rules. The courts who appoint the evaluators will be responsible for enforcing these rules.

The new version of Subchapter O implements the new language of the statute, clarifies the new law, and updates the minimum requirements for the pre-placement and post-placement portions of an adoption evaluation.

A summary of the changes follows:

New §745.9041 defines the words to be used in this subchapter, including the new terms "adoption evaluation" and "adoption evaluator."

New §745.9043 states that the purpose of this subchapter is to establish minimum requirements for the pre-placement and post-placement portions of an adoption evaluation.

New §745.9045 clarifies that the rules in this subchapter only apply to independent adoptions and do not apply to adoption evaluations conducted by DFPS employees, DFPS contractors, or CPAs.

New §745.9047 specifies the requirements for an adoption evaluator to make assessments, conclusions, and recommendations when conducting an adoption evaluation.

New §745.9049 clarifies that an adoption evaluator may not consider an adoptive parent's membership in the armed forces as a negative factor in an adoption evaluation.

New §745.9051 requires an adoption evaluator to report suspicious illegal adoptive placements to DFPS.

New §745.9053 clarifies that usually the pre-placement portion of an adoption evaluation is conducted before the child begins living in the adoptive parents' home.

New §745.9055 specifies the information about the child that is required in the pre-placement portion of an adoption evaluation.

New §745.9057 specifies the information about the adoptive parents that is required in the pre-placement portion of an adoption evaluation.

New §745.9059 specifies who must be interviewed during the pre-placement portion of an adoption evaluation.

New §745.9061 clarifies the interview documentation requirements for the pre-placement portion of an adoption evaluation.

New §745.9063 clarifies the requirements for visiting the adoptive parents' home when conducting the pre-placement portion of an adoption evaluation.

New §745.9065 clarifies the requirements for assessing the adoptive parents' home and grounds when conducting the pre-placement portion of an adoption evaluation.

New §745.9067 requires additional screening of the adoptive parents when they have previously been screened to be adoptive parents or foster parents by another CPA.

New §745.9069 specifies the information about the child's birth parents that is required in the pre-placement portion of an adoption evaluation.

New §745.9071 clarifies that updates are recommended if the adoptive child is not placed with the adoptive parents within six months of the completion of the pre-placement portion of an adoption evaluation.

New §745.9073 clarifies that an update is required if the adoptive parents plan to adopt another child, either in addition to or instead of the child for whom the pre-placement portion of an adoption evaluation was completed.

New §745.9075 clarifies the requirements for an update of the pre-placement portion of an adoption evaluation.

New §745.9077 specifies the written information that must be included in the pre-placement portion of an adoption evaluation report.

New §745.9079 clarifies that the pre-placement and post-placement portions of an adoption evaluation and reports may be combined and a single report completed when the suit for adoption is filed after the child began living in the adoptive parents' home.

New §745.9081 clarifies that the interviews for the post-placement portion of an adoption evaluation must be conducted after the child has resided in the adoptive parents' home for at least five months. However, the gathering of written information for the post-placement portion of an adoption evaluation may start after the child begins living in the adoptive parents' home.

New §745.9083 specifies who must be interviewed during the post-placement portion of an adoption evaluation.

New §745.9085 clarifies what issues must be addressed in the interviews for the post-placement portion of an adoption evaluation.

New §745.9087 clarifies the interview documentation requirements for the post-placement portion of an adoption evaluation.

New §745.9089 clarifies the requirements for visiting the adoptive parents' home when conducting the post-placement portion of an adoption evaluation.

New §745.9091 specifies the written information that must be included in the post-placement portion of an adoption evaluation report.

New §745.9093 clarifies that the adoptive parents, adoptive parents' attorney, or the adoption evaluator must request: (1) a fingerprint based criminal history background check from the Department of Public Safety and the Federal Bureau of Investigations; and (2) a central registry background check from DFPS.

New §745.9095 clarifies that the adoption evaluator may also request from DFPS a complete, unredacted copy of any investigative record regarding abuse or neglect that relates to any person residing in the adoptive parents' home.

New §745.9097 clarifies that the adoptive parents are entitled to receive a copy of the pre-placement and post-placement portions of the adoption evaluation reports before the court issues a final order regarding the adoption.

New §745.9098 explains to the adoptive parents who they or their attorney may contact regarding a complaint on how the adoption evaluation was conducted, including: (1) the court that ordered the adoption evaluation; and/or (2) the board that licenses the person who primarily conducted the adoption evaluation, if applicable.

The sections will function by being in compliance with Texas Family Code, §107.159(a) and §107.160(a); and strengthening the adoption evaluation process.

No comments were received regarding adoption of the sections.

SUBCHAPTER O. INDEPENDENT COURT-ORDERED ADOPTION EVALUATIONS DIVISION 1. DEFINITIONS, PURPOSE, AND SCOPE

40 TAC §§745.9041, 745.9043, 745.9045

The new sections are adopted under Human Resources Code (HRC) §40.0505 and Government Code §531.0055, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services; and HRC §40.021, which provides that the Family and Protective Services Council shall study and make recommendations to the Executive Commissioner and the Commissioner regarding rules governing the delivery of services to persons who are served or regulated by the department.

The new sections implement portions of HB 1449, which adds Subchapter E, Adoption Evaluations, to Chapter 107 of the Texas Family Code. More specifically, these modifications primarily implement §§107.151, 107.152, 107.159(a), and 107.160(a).

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Trevor Woodruff

General Counsel

Department of Family and Protective Services

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For further information, please call: (512) 438-5559



DIVISION 2. MAKING ASSESSMENTS, CONCLUSIONS, AND RECOMMENDATIONS

40 TAC §§745.9047, 745.9049, 745.9051

The new sections are adopted under Human Resources Code (HRC) §40.0505 and Government Code §531.0055, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services; and HRC §40.021, which provides that the Family and Protective Services Council shall study and make recommendations to the Executive Commissioner and the Commissioner regarding rules governing the delivery of services to persons who are served or regulated by the department.

The new sections implement portions of HB 1449, which adds Subchapter E, Adoption Evaluations, to Chapter 107 of the Texas Family Code (TFC). More specifically, these modifications primarily implement §§107.151, 107.158, 107.159(a), and 107.160(a) and TFC, §162.0025.

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Trevor Woodruff
General Counsel
Department of Family and Protective Services
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For further information, please call: (512) 438-5559



DIVISION 3. MINIMUM REQUIREMENTS FOR THE PRE-PLACEMENT PORTION OF AN ADOPTION EVALUATION AND REPORT

40 TAC §§745.9053, 745.9055, 745.9057, 745.9059, 745.9061, 745.9063, 745.9065, 745.9067, 745.9069, 745.9071, 745.9073, 745.9075, 745.9077, 745.9079

The new sections are adopted under Human Resources Code (HRC) §40.0505 and Government Code §531.0055, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services; and HRC §40.021, which provides that the Family and Protective Services Council shall study and make recommendations to the Executive Commissioner and the Commissioner regarding rules governing the delivery of services to persons who are served or regulated by the department.

The new sections implement portions of HB 1449, which adds Subchapter E, Adoption Evaluations, to Chapter 107 of the Texas Family Code. More specifically, these modifications primarily implement §107.151 and §107.159(a).

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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General Counsel
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DIVISION 4. MINIMUM REQUIREMENTS FOR THE POST-PLACEMENT PORTION OF AN ADOPTION EVALUATION AND REPORT

40 TAC §§745.9081, 745.9083, 745.9085, 745.9087, 745.9089, 745.9091

The new sections are adopted under Human Resources Code (HRC) §40.0505 and Government Code §531.0055, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services; and HRC §40.021, which provides that the Family and Protective Services Council shall study and make recommendations to the Executive Commissioner and the Commissioner regarding rules governing the delivery of services to persons who are served or regulated by the department.

The new sections implement portions of HB 1449, which adds Subchapter E, Adoption Evaluations, to Chapter 107 of the Texas Family Code. More specifically, these modifications primarily implement §107.151 and §107.160(a).

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Trevor Woodruff
General Counsel
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DIVISION 5. BACKGROUND CHECK INFORMATION

40 TAC §745.9093, §745.9095

The new sections are adopted under Human Resources Code (HRC) §40.0505 and Government Code §531.0055, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services; and HRC §40.021, which provides that the Family and Protective Services Council shall study and make recommendations to the Executive Commissioner and the Commissioner regarding rules governing the delivery of services to persons who are served or regulated by the department.

The new sections implement portions of HB 1449, which adds Subchapter E, Adoption Evaluations, to Chapter 107 of the Texas Family Code. More specifically, these modifications primarily implement §§107.151, 107.159(a), and §107.163.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Trevor Woodruff
General Counsel
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DIVISION 6. COPIES OF ADOPTION EVALUATION REPORTS AND COMPLAINTS

40 TAC §§745.9097, 745.9098

The new sections are adopted under Human Resources Code (HRC) §40.0505 and Government Code §531.0055, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services; and HRC §40.021, which provides that the Family and Protective Services Council shall study and make recommendations to the Executive Commissioner and the Commissioner regarding rules governing the delivery of services to persons who are served or regulated by the department.

The new sections implement portions of HB 1449, which adds Subchapter E, Adoption Evaluations, to Chapter 107 of the Texas Family Code. More specifically, these modifications primarily implement §§107.151, 107.159(d), and 107.160(d).

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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SUBCHAPTER O. INDEPENDENT COURT-ORDERED SOCIAL STUDIES

DIVISION 1. DEFINITIONS

40 TAC §§745.9060, 745.9061, 745.9063

The repeals are adopted under Human Resources Code (HRC) §40.0505 and Government Code §531.0055, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services; and HRC §40.021, which provides that the Family and Protective Services Council shall study and make recommendations to the Executive Commissioner and the Commissioner regarding rules governing the delivery of services to persons who are served or regulated by the department.

The repeals implement portions of HB 1449, which adds Subchapter E, Adoption Evaluations to Chapter 107 of the Texas Family Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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DIVISION 2. MINIMUM QUALIFICATIONS AND OTHER REQUIREMENTS

40 TAC §§745.9065, 745.9067, 745.9068

The repeals are adopted under Human Resources Code (HRC) §40.0505 and Government Code §531.0055, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services; and HRC §40.021, which provides that the Family and Protective Services Council shall study and make recommendations to the Executive Commissioner and the Commissioner regarding rules governing the delivery of services to persons who are served or regulated by the department.

The repeals implement portions of HB 1449, which adds Subchapter E, Adoption Evaluations to Chapter 107 of the Texas Family Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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DIVISION 3. PRE-ADOPTIVE SOCIAL STUDIES

40 TAC §§745.9069 - 745.9071, 745.9073, 745.9075, 745.9077, 745.9079, 745.9081, 745.9083, 745.9085, 745.9087, 745.9089, 745.9090

The repeals are adopted under Human Resources Code (HRC) §40.0505 and Government Code §531.0055, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services; and HRC §40.021, which provides that the Family and Protective Services Council shall study and make recommendations to the Executive Commissioner and the Commissioner regarding rules governing the delivery of services to persons who are served or regulated by the department.

The repeals implement portions of HB 1449, which adds Subchapter E, Adoption Evaluations to Chapter 107 of the Texas Family Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Trevor Woodruff

General Counsel

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For further information, please call: (512) 438-5559



DIVISION 4. POST-PLACEMENT ADOPTIVE SOCIAL STUDY AND REPORT

40 TAC §§745.9091 - 745.9097

The repeals are adopted under Human Resources Code (HRC) §40.0505 and Government Code §531.0055, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services; and HRC §40.021, which provides that the Family and Protective Services Council shall study and make recommendations to the Executive Commissioner and the Commissioner regarding rules governing the delivery of services to persons who are served or regulated by the department.

The repeals implement portions of HB 1449, which adds Subchapter E, Adoption Evaluations to Chapter 107 of the Texas Family Code.

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Trevor Woodruff

General Counsel

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For further information, please call: (512) 438-5559

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DIVISION 5. COMPLAINTS

40 TAC §745.9100

The repeal is adopted under Human Resources Code (HRC) §40.0505 and Government Code §531.0055, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services; and HRC §40.021, which provides that the Family and Protective Services Council shall study and make recommendations to the Executive Commissioner and the Commissioner regarding rules governing the delivery of services to persons who are served or regulated by the department.

The repeal implements portions of HB 1449, which adds Subchapter E, Adoption Evaluations to Chapter 107 of the Texas Family Code.

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Trevor Woodruff

General Counsel

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For further information, please call: (512) 438-5559



CHAPTER 748. MINIMUM STANDARDS FOR GENERAL RESIDENTIAL OPERATIONS SUBCHAPTER A. PURPOSE AND SCOPE

40 TAC §748.7

On behalf of the Department of Family and Protective Services (DFPS), the Health and Human Services Commission adopts new §748.7, concerning the applicability of Chapter 42, Human Resources Code, and licensing rules and statutes in general to family residential centers operated by contractors of U.S. Immigration and Customs Enforcement (ICE), with changes to the proposed text as published in the November 13, 2015, issue of the *Texas Register* (40 TexReg 8009).

The justification for §748.7 is to define the term "family residential center" (FRC) and to make FRCs subject to regulation as General Residential Operations (GROs). Requiring FRCs to comply with all requirements for GROs will be more protective of children than taking no action regarding the provision of child care without a license.

DFPS first adopted §748.7 on an emergency basis effective September 2, 2015 as published in the September 18, 2015, issue of the *Texas Register* (40 TexReg 6229). The emergency rule tailored minimum standards for GROs to FRCs so that DFPS could most effectively regulate them. In its publication of the emergency rule, DFPS cited that the July 24, 2015 ruling of *Flores v. Johnson*, CV 85-4544 DMG (C.D. Cal. July 24,

2015) "highlighted a gap in the oversight of the children" housed in family residential centers. DFPS found that there was an imminent peril to the public's health, safety, or welfare due to the lack of "comprehensive oversight of the care of children housed in the facilities by an independent agency." *Id.*

Grassroots Leadership, Inc., a non-profit organization, filed suit seeking declaratory and injunctive relief from the emergency rule on September 30, 2015, in the 353rd District Court in Travis County. Judge Karin Crump of the 250th Travis County District Court granted a Temporary Restraining Order halting the adoption and implementation of the emergency rule on September 30, 2015. *Grassroots v. TDFPS*, No. D-1-GN-15-004336 (353rd Dist. Ct., Travis County, Tex. Sept. 30, 2015). On November 20, 2015, Judge Crump issued a Temporary Injunction halting the adoption of the emergency rule until a trial on the merits can be held on May 9, 2016. *Grassroots v. TDFPS*, No. D-1-GN-15-004336 (353rd Dist. Ct., Travis County, Tex. Nov. 20, 2015). The Court specifically held that the Temporary Injunction did not preclude DFPS "from proceeding with traditional rule adoption procedures." *Id.* at 7. Accordingly, DFPS published §748.7 as a proposed rule in the November 13, 2015, issue of the *Texas Register* (40 TexReg 8009).

The adoption of the rule ensures the continued protection of children housed in the facilities by making the facilities subject to the regulatory authority of CCL along with its associated requirements, with limited exception.

The section will function by enhancing the quality of care for children housed in FRCs.

The essence of the new rule is the application of Child-Care Licensing's (CCL's) regulations related to GROs to FRCs, as defined in the rule. That definition, found in subsection (a), applies regulations for GROs to FRCs that are operated by or under contract with ICE to enforce federal immigration laws and that detain children who remain with parents or other adult family members, who provide direct care for the child except in specific circumstances. The definition currently would apply only to the South Texas Family Residential Center (STFRC) operated by the Corrections Corporation of America in Dilley, Texas, and the Karnes County Residential Center operated by the GEO Group, Inc. in Karnes City, Texas.

Subsection (b) classifies the FRCs as GROs and requires them to comply with all associated requirements unless CCL issues a waiver or variance, or an exception is granted by the section itself. While the rule applies the standards to the FRCs and does not go into extensive detail regarding those standards, incorporating the standards for GROs by reference means incorporating a broad and comprehensive regulatory scheme designed to protect and enhance the well-being of children in care. As is discussed in additional detail in DFPS' responses to public comments received on the proposed rule, the regulatory overlay in place for GROs involves statutory mandates and direction, rules general applicable to all regulated operations including GROs which are found in Chapter 745 of this title, Licensing, as well as Minimum Standards specific to GROs found in Chapter 748 of this title. Those Minimum Standards include governing requirements across many domains that range from the qualifications for the Child Care Administrator each facility must employ to requirements for food storage to restrictions on the use of emergency behavior intervention.

Subsection (b) further clarifies that DFPS does not oversee requirements that pertain to other law. Of particular relevance to

the comments received to the proposed rule, DFPS explicitly clarifies that it has no role in determining whether the FRC is classified as secure.

Subsection (c) lists several exceptions that DFPS determined at the outset were appropriate in recognition of the unique character of the FRCs. First, because children are housed with parents or family members, and there may be sibling groups of more than four children, DFPS recognized that the limitation on four room occupants could be directly at odds with the need to house families together wherever possible and safely achievable. Secondly, because children would be sharing rooms with parents or other family members, DFPS recognized that the FRCs would not be required to comply with all of the requirements related to children sharing a bedroom with an adult. Finally, because siblings may be of the opposite gender, and because there may be circumstances where young children of different families would be housed together, DFPS granted a partial exception to the limitations on children of the opposite gender sharing a room. It should be emphasized that the text of the subsection noted that the facilities would not be required to comply with *all* of the provisions in the referenced standards, which makes clear that the FRCs may be required to comply with portions of the standards in question. Furthermore, and more significantly, DFPS reiterated in subsection (d) its ultimate discretion to place conditions on any exceptions and described some examples of such conditions by way of illustration. Specifically, DFPS offered a non-exhaustive list of possible conditions on the exceptions to allow flexibility in the agency's exercise of its authority in recognition of its responsibility for overseeing the safety and well-being of children in care, which include: limits on the number of room occupants to meet fire safety standards, or limitations on allowing children of opposite genders to share a room only if they are in the same family. DFPS then reiterated its discretion to place "any other limitation determined by the department to be necessary to the health, safety, or welfare of children in care."

Finally, in subsection (e) DFPS added a provision again in recognition of the FRCs' unique characteristics, which requires any documentation DFPS deems necessary to clarify the division of caretaking responsibility between FRC staff and the parents or family of a child in care. DFPS must not merely receive the documentation but must also approve it during the application process and at the point of any subsequent amendments to the documentation.

During the public comment period, DFPS sought public feedback regarding the proposed rules through multiple channels. In total, DFPS received 1486 comments in writing. DFPS received 3 responses through the U.S. Postal Service that were not also received either through email or in hard copy at the public meeting on the rule.

In total DFPS received 1460 responses via email. Of those responses, 701, or 48 percent were received from individuals or groups who reside outside the state of Texas. The vast majority of the comments (approximately 1350) were comprised of two standardized emails. The first of the two standardized emails appears to have been issued primarily in response to the emergency rule adopted by DFPS on September 2, 2015, the implementation of which was temporarily enjoined by the 250th District Court in Austin on November 12, 2015. Indeed, 488 of those comments were received prior to the publication of the proposed rule and could not, therefore, have been in response to the publication of the proposed rule. However, because the comments appear to be directed both at the emergency rule adoption as

well as the substance of the rule and because several of the standardized emails were received following publication of the proposed rule, DFPS considered the substance of the standardized email in its discussion of comments and the agency's response. DFPS also considered the substance of the second standardized email, which opposed licensing the FRCs, and incorporated the substance into the summaries of the comments.

In addition, DFPS announced that it would hold a public meeting on the rule proposal on December 9, 2015, in the following ways: (1) in the *Texas Register* Open Meetings section; (2) through the govdelivery.com service, which allows interested persons to sign up for email or text updates regarding DFPS or other governmental agencies; and (3) on the DFPS website page for items of interest to stakeholders. The meeting was well attended and received media coverage. Forty-five people testified, some in their individual capacities and others on behalf of an organization or group. In addition, 11 speakers handed in individual written testimony. An advocacy group submitted approximately 800 written comments to the panel of DFPS and HHSC representatives present to take testimony. DFPS subsequently determined that all but 12 of those printed comments were identical printouts to emails previously received by DFPS. The entire meeting was transcribed and published on the DFPS public website at http://www.dfps.state.tx.us/About_DFPS/Public_Meetings/Stakeholders/documents/2015-12-09-Licensing_Hearing_transcript_acc.pdf.

The public comments received by the agency included those submitted by interested groups or associations, as well as legislators in their official capacity. Specifically, the groups and officials submitted comments generally in opposition to the adoption of the rule include: the Interfaith Welcome Coalition; the Texas School of Law Immigration Clinic; Methodist Healthcare Ministries of South Texas; the Texas Catholic Conference; the Benedictine Sisters; CARA Family Detention Pro Bono Project (comprised of the Catholic Legal Immigration Network, Inc.; the American Immigration Council; the Refugee and Immigrant Center for Education and Legal Services; and the American Immigration Lawyers Association); Heartland Alliance's National Immigrant Justice Center; Texas Pediatric Society; Rio Grande Equal Voice Network; Representative Trey Martinez Fischer, Chairman, Texas Mexican American Legislative Caucus; Texas Senators: Judith Zaffirini, José Rodríguez, José Menéndez, Sylvia R. Garcia, Rodney Ellis, Juan "Chuy" Hinojosa, John Whitmire, and Kirk Watson; the De Anda Law Firm; CASA Latina; Mexican American Legal Defense and Education Fund; Grassroots Leadership; Unitarian Universalist Service Committee; Texas Impact; Women's Refugee Commission; American Civil Liberties Union of Texas; Unitarian Universalist Association; National Association of Social Workers, Texas Chapter (NASW); and Catholic Charities of the Rio Grande Valley.

The following groups and officials submitted comments generally supporting the adoption of the rule: Representative James White and a representative of the Karnes County Residential Center.

Finally, while not formal public comment, the rule proposal was covered in various media outlets. Included in the coverage were two editorial pieces regarding the proposed rule. The Fort Worth Star-Telegram on December 10, 2015, noted that the testimony in the public meeting was to the effect that the family residential centers have "a long way to go" to provide care to children. The Star-Telegram further indicated that it was "a shame" licensure by DFPS had taken so long. In addition, the San Antonio Express News on December 15, 2015, noted that so long as

women and children are being detained in the facilities, the state has some obligation to oversee the care of children who are detained there.

All of the public comments, whether submitted via mail, email or orally in the public meeting, were reviewed and considered by DFPS staff. The feedback generally fell into themes, which are summarized below, along with the agency's response.

(1) Comments Supporting Licensure As a Means to Protect Children and Improve Current Practice:

Comment: Two commenters, including one state representative, supported licensure. The representative noted that the state is statutorily obligated to ensure the safety and wellbeing of all children in Texas, and by providing oversight to the FRCs, DFPS would be able to ensure the children's safety and pass on its institutional knowledge of child safety and wellbeing to the federal government. The commenter further noted that by expanding its regulatory purview, DFPS would be able to play a vital role in identifying and providing services to children and families that are at high risk of human trafficking. Another commenter, who provides representation to one of the FRCs, noted that licensure is not merely an endorsement of the status quo as the FRCs would not only be required to meet the standards of a GRO, but would be required to provide evidence of compliance. The commenter cited to the significant fiscal impact to the FRCs to come into compliance with the proposed requirements, including increasing staff to detainee ratio, recruiting qualified staff to provide necessary services mandated by the rule, meeting the public hearing requirements, ensuring CPR certifications, obtaining background checks for employees, meeting square footage requirements, and submitting materials clarifying the supervisory and caretaking responsibilities of staff and family members. The commenter also noted that the exemptions to minimum standards, which DFPS has authority to place limits on, were formulated to allow children to continue residing with their mothers and not to continue the status quo.

Response: DFPS agrees with the comments.

(2) Comments Expressing Concern with Licensure and Any Exemptions, Waivers, or Variances Associated with Licensure:

Comment: A significant number of commenters expressed concern that licensing the Karnes County and Dilley Centers with exemptions, as the rule allows, would amount to the mere rubber stamping of the centers as they currently operate without meaningful consideration of their ability to provide adequate child care. Specifically, the commenters argued that the rule would not ameliorate the conditions of the centers, but would rather allow the centers to continue operating as detention centers in a manner that is contrary to the safety and well-being of children. One commenter noted that the Karnes County center has a history of temporarily altering its conditions, such as redecorating, providing extra toys, and improving food quality, in preparation for visitations by external entities; however, it has not made significant and permanent improvements. According to the commenters, licensure would not change the inherent purpose and overall substandard environment of the Karnes County and Dilley centers.

Response: The Texas regulatory scheme in place for GROs is comprehensive, extensive, and rooted in basic tenets of child protection and welfare. By properly designating the FRCs as GROs, DFPS brings to bear not only the single rule adopted here but a host of statutory, regulatory, and policy-based requirements aimed directly at protecting the health, safety, and

well-being of children in care. (See HRC §42.001). First, the Texas legislature has established the basic framework for the licensure of child-care facilities, primarily in CCL's enabling authority in HRC Chapter 42, as well as DFPS' general enabling statutes in HRC Chapter 40. (See in particular HRC §40.002(b)). The legislature has directed CCL, through the Executive Commissioner of HHSC, to adopt rules and standards to accomplish various purposes including: promoting the health, safety, and welfare of children; ensuring adequate supervision of children by capable, qualified, and healthy personnel; and ensuring that facilities follow the directions of health care professionals. (See HRC §42.042(e)). In addition to general direction to promulgate standards, the legislature has mandated certain critical aspects of the licensure process and its underlying requirements. For example, the Texas legislature has enacted laws related to the requirement for submission of an application (see HRC §42.046); requirements related to conducting and abiding by the results of criminal and abuse/neglect history checks (see HRC §42.056); the requirement that each facility hire and maintain a licensed child-care administrator for the facility (see HRC Chapter 43); and the requirement that a potential operation convene a public hearing in counties of a certain population size (see HRC §42.0461).

Based on its general statutory authority and duties, CCL has adopted a broad regulatory framework in Chapter 745 of this title, Licensing, contains rules of general applicability to various operations regulated by the agency. Of particular significance to this rule, Chapter 745 contains requirements and restrictions related to the criminal or abuse/neglect history of a person employed or present at the facility. (See Chapter 745, Subchapter F, Background Checks).

Next, CCL has various rule chapters in place recognizing the different operation types and the services they provide. (See HRC §42.042(f) and (g)). The various subchapters in this chapter related to GROs address a multitude of topics, many of which are discussed in greater detail in this preamble, including requirements related to training for staff, the provision of medical and dental care, the use of emergency behavior intervention. Examples of other topics covered by regulation and not discussed in great detail in this preamble include: requirements related to admission and service planning, the physical site of the operation, and transportation. Should there be any further question regarding the content of DFPS' standards, all are readily available to the public, both through the Secretary of State's website for the Texas Administrative Code (see [http://texreg.sos.state.tx.us/public/readtac\\$ext.ViewTAC?tac_view=3&ti=40&pt=19](http://texreg.sos.state.tx.us/public/readtac$ext.ViewTAC?tac_view=3&ti=40&pt=19)) and DFPS' website (see http://www.dfps.state.tx.us/Child_Care/Child_Care_Standards_and_Regulations/default.asp). Moreover, the entire policy handbook in use by CCL staff is publicly available at any time (see <https://www.dfps.state.tx.us/handbooks/Licensing/default.asp>).

Against this extensive regulatory backdrop, the FRCs would be required to go through the same process as other GROs in the state and to demonstrate compliance with the various requirements of Texas statute and regulation discussed herein. First, they would be required to submit an application. Residential Child Care Licensing (RCCL) has 21 days to accept the application. (See §745.301 of this title (relating to How long does Licensing have to review my application and let me know my application status?)). During that time, RCCL reviews the application for completeness and ensures that policies and procedures that are required at application are included, and that applicable

fees have been paid. At times, RCCL may need to request additional information or clarification from the GRO in order to accept the application or RCCL may return the application.

Once the application is accepted, RCCL has up to two months to complete a Standard by Standard inspection to evaluate compliance with Minimum Standards. (See §745.321 of this title (relating to What will Licensing do after accepting my application?)). Concurrently, in counties with a population of less than 300,000 people, the GRO has one month from the date the application was accepted to hold a public hearing. (See §745.275(2)(C) of this title (relating to What are the specific requirements for a public notice and hearing?)). Notice of the public hearing must be published at least ten days prior to the date of the hearing in a newspaper of general circulation in a community where the services will be provided. (HRC §42.061(b) and §745.275(1) of this title (relating to What are the specific requirements for a public notice and hearing?)).

Once the public hearing occurs, the GRO has ten working days to submit a verbatim record of the hearing and a complete comment summary report to RCCL. (See §745.275(2)(C) of this title (relating to What are the specific requirements for a public notice and hearing?)). RCCL has two months after the date of the complete application being accepted to issue or deny the initial permit unless there is good cause to extend the timeframe, such as reviewing extensive comments of a public hearing. (See §745.321 of this title (relating to What will Licensing do after accepting my application?)).

RCCL may deny the application if the operation fails to comply with Minimum Standards, administrative rules, or the law. HRC §42.072(a) and §745.8605 of this title (relating to When can Licensing take remedial action against me?) further authorizes certain remedial actions related to failure to comply with aspects of the application process. Additionally, RCCL may deny the permit if information obtained through the public hearing process indicates licensure is inappropriate. (HRC §42.0461(e), §745.279 of this title (relating to How may the results of a public hearing affect my application for a permit or a request to amend my permit?), and §745.8605(21) of this title (relating to When can Licensing take remedial action against me?)).

When an initial permit is issued, it is valid for a period of six months. (HRC §42.051 and §745.347 of this title (relating to How long is an initial permit valid?)). During the initial permit period, RCCL will generally conduct a minimum of three unannounced inspections to determine compliance with Minimum Standards, administrative rules, and law. (§745.351 of this title (relating to If I have an initial permit, when will I be eligible for a non-expiring permit?)). If during the first initial permit period, the GRO fails to establish continued compliance and additional time is necessary to determine a pattern of compliance, RCCL may issue a second initial permit to establish ongoing compliance. If the second initial permit is issued, RCCL will again conduct at least three unannounced inspections. If after the first initial permit period or the second initial permit period, the GRO has established continued compliance, RCCL may issue a full permit. When a GRO is issued a full permit, RCCL will conduct at least one unannounced inspection per year, in addition to any other inspections or investigations that may be necessary as a result of reports received. (§745.8407 of this title (relating to When will Licensing inspect and/or investigate an operation?)).

The purpose of this rule is to apply the licensure requirements to the operations, a necessary byproduct of which is that they will come into compliance with said requirements. If a current prac-

tice is inconsistent with CCL standards, then the practice would be addressed in the licensure process. To argue that a given practice does not *currently* comply with regulations for child-care is to misapprehend the purpose of licensure and all that it entails.

Comment: Several commenters opposed the exceptions to Minimum Standards contained in the proposed rule stating that they are overbroad, arbitrary and capricious, set a dangerous precedent for regulating childcare facilities, and essentially allow the FRCs to continue operating under the status quo of a prison. The commenters noted that federal and state law do not provide any basis for lowering the standards for facilities that house accompanied minors as opposed to unaccompanied minors. They further noted that the exemptions effectively create a second-class of children subject to a lower, disparate standard from children under the custody of DFPS or unaccompanied minors. Several commenters expressed concern that the exceptions not only fail to address the problems of abuse and neglect, but increase the risk of physical and sexual abuse and maltreatment by allowing different genders and unrelated family members to be housed together in large numbers. One commenter noted that there have already been numerous allegations of assault and potential sexual abuse because of the lack of age and gender restrictions, and another commenter noted that the exemptions compromise the families' ability to file complaints for poor living conditions and abuse and neglect. While some commenters acknowledged a need for oversight, they contended that DFPS should only adopt rules consistent with those for child care facilities by requiring the FRCs to meet all current minimum standards and ensure appropriate therapeutic and trauma-informed settings as is required for other GROs.

Response: From the outset, DFPS recognized that the character of the FRCs is without an identical counterpart in the current regulatory structure. Children are housed with their mothers or other adult family members, yet by virtue of being divested of some or all of their authority to direct the daily activities, place of residence, and other aspects of their children's lives, the mothers cannot be considered the sole caregivers as they would be outside the setting. Moreover, while the families are generally housed together, there are times in which a mother may be separated from her child, e.g. when capacity is extremely high and some of the children are housed in a common, dormitory-like fashion. To the extent the mothers are not exercising full parental control, and may not be with their children at a given time, the staff in the FRCs are assuming child-care responsibilities, and it is important that this care receives oversight from the cognizant state agency.

However, in recognition of the uniqueness of the setting, DFPS included several exceptions to Minimum Standards in both the emergency rule and the rule now under consideration. The first exception, related to the limitation on the number of room occupants is intended to permit living arrangements that preserve family units. DFPS included in subsection (d) of the rule language to clarify that there may be conditions related to the outer limit on the number of occupants, particularly where such a limit is necessary to comply with fire safety standards. DFPS will require a minimum of sixty square feet per child, and as discussed herein, DFPS applies exceptions, waivers and variances in light of their potential implications to child safety, and would not implement the exception such that it was inconsistent with its child protection obligations.

The second exception in the rule relates to children sharing a bedroom with an adult, and is intended to permit children to sleep

in a room with their mothers. While DFPS' current standards related to adults sharing a bedroom with children relates to adults who are in care at the facility, unlike the mothers at the FRCs who are not in care, DFPS felt it was important to clarify from the outset that the limitation would be flexibly applied. Again, subsection (d) as well as DFPS' overall regulatory authority means that the exception is not unfettered, and DFPS may place conditions on it appropriate to the circumstances.

The third exception, like the others, is intended to permit the preservation of family units and may be tempered by any limitations DFPS deems appropriate. This particular exception relates to children of the opposite gender sharing a room. DFPS understands the concerns of commenters related to potential misconduct. However, DFPS intends to permit children of the opposite gender to share a room only if they are members of the same family or under the age of six. The goal of the exception is to strike a balance between family preservation within the current facility and the paramount concern of child safety.

However, because the rule text initially generated confusion and concern regarding the scope and purpose of the exceptions, DFPS has modified the proposed text to provide further clarification. First, the exception regarding the limitation on room occupants has been modified to make explicit that the number of children permitted in the room will be based on the square footage of the room, with no fewer than sixty square feet per child. Second, the exception related to children sharing a bedroom has been clarified to specify that the exception relates to children remaining with their own family. Third, the exception permitting children of the opposite gender to share a bedroom has been amended so that children from different families who are opposite gender may not share a bedroom unless they are under the age of 6. Finally, DFPS incorporates by reference in subsection (d) its regulation in §745.8313 of this title (relating to Is a waiver or variance unconditional?), which makes it explicit that DFPS retains the discretion to place conditions on any waiver or variance, as well as the exceptions contained in §748.7.

Comment: One commenter suggested that in light of the aim of the regulation to preserve family units, subsection (c) be modified to preface the exceptions with the language "Because the designated facilities house mothers with their children..."

Response: DFPS declines to make the change. By definition which is part of the rule, an FRC is a facility in which a child is detained with the child's mother or other family member, and the adult or other family member provides direct care and supervision. For this reason, DFPS views the change as substantively unnecessary.

Comment: Similarly to previous comments regarding the exceptions contained in the rule text, several commenters raised concerns that because DFPS may grant a waiver or variance to a Minimum Standard, in addition to the exceptions listed in the published rule, child safety could be compromised and there may be a disparate standard for unaccompanied minors compared to those housed with their mothers in the FRCs.

Response: It is true that all GROs, including the FRCs, are potentially eligible for a waiver or variance of a particular standard. However, the issuance of any waiver or variance is guided by published standards and policy and tempered always by the need to protect children.

Waivers and variances are tools to assist child-care providers to comply with standards within a specified period of time, without compromising the safety of children served by the

operation. A waiver or variance is not an entitlement. (See §745.8301 of this title (relating to What if I cannot comply with a specific minimum standard?)). Staff must evaluate the risk to children, along with several other specified variables, before granting approval for a waiver or variance. (See §745.8307 of this title (relating to How does Licensing make the decision to grant or deny my waiver or variance request?)), and Licensing Policy and Procedures Handbook Section 5110 (available at https://www.dfps.state.tx.us/handbooks/Licensing/Files/LPPH_pg_5000.asp#LPPH_5100)). A waiver or variance may not be granted if child safety would be negatively impacted. All waivers and variances, and any conditions placed on the waivers and variances, are time limited, and may be revoked or amended by CCL at any time if appropriate. (See §745.8317 of this title (relating to Can Licensing amend or revoke a waiver or variance, including its conditions?)). When granting a waiver or variance, conditions must be put into place to ensure that children are not at risk. (See §745.8313 of this title (relating to Is a waiver or variance unconditional?)) Such conditions must be easily observable and measurable by CCL staff as well as the caregivers in the facility. Licensing Policy & Procedure Handbook Section 5120 (available at http://www.dfps.state.tx.us/handbooks/Licensing/Files/LPPH_pg_5000.asp#LPPH_5120) Conditions are another way of achieving compliance with minimum standards and reducing risk to children. Conditions must be evaluated during each inspection and during each investigation relevant to the standard and the conditions. *Id.*

(3) Comments Relating to Problems with Detention in General and in the Individual FRCs:

Comment: Several commenters expressed opposition to the proposed rule on the grounds that the FRCs DFPS is seeking to license are not child care centers but rather detention centers designed to house individuals in the custody of ICE during immigration proceedings. Commenters argued that although the children are housed with their mothers, the mothers are stripped of authority to make decisions for their children's well-being. Commenters stated that the centers are similar to prisons in that they are enclosed within tall walls and barbed wire fences; house a large number of individuals rather than adhere to any specific child-to-provider ratio; require the families to submit to badge checks several times a day and pass through electronically locked doors for access to basic areas; limit and monitor access to telephones and computers which are provided to families at a monetary cost; discipline the families through the use of pepper spray and harsh consequences for children's misbehavior; threaten to remove children from mothers for failure to follow rules or if complaints are made; and house unrelated adults and children of different genders together in small non-private spaces. Many commenters further noted that the centers are operated by private prison corporations and staffed by individuals with backgrounds in law enforcement rather than individuals with experience and training in child care. Commenters also noted that simply hiring more staff with a background in law enforcement rather than child care will not change conditions in the FRCs.

Response: In both the rule and this adoption preamble, DFPS has stressed repeatedly that whether the FRC is operated as a detention or secure FRC is outside its purview. However, precisely because it appears that the mothers in the FRCs are divested of some or even all of their parental authority (when separated from their children, for example), DFPS has concluded that the FRCs and their staff are providing child care. The purpose of

licensure is to ensure compliance with the standards for the provision of such care. Those standards, as previously discussed, are robust. Of particular relevance to this question, there are many standards that relate to the appropriate use of discipline and punishment found in Subchapter M of this chapter (relating to Administrative Reviews and Due Process Hearings). There are detailed standards regarding the limited use of Emergency Behavior Intervention (EBI) found in Subchapter N of this chapter (relating to Administrator Licensing).

Next, while it may be true that the FRCs have heretofore hired staff with law enforcement experience, this does not translate inexorably to the same practices continuing in the future, nor does it alter the FRCs' obligation to comply with the child-care related training requirements placed on GROs by Minimum Standards. While the training requirements vary somewhat based on the services provided in a particular GRO, any caregiver at a licensed operation must participate in orientation, pre-service training, and annual training. Orientation gives the caregiver the opportunity to learn about the philosophy, organizational structure, policies, and a description of the services and programs the operation offers, as well as the needs and characteristics of children that the operation serves. Pre-service training focuses on topics relevant to job duties and must include, *inter alia*, content on appropriate discipline; child development; measures to identify, treat, and report suspected abuse, neglect and exploitation; and safety and emergency procedures. See §748.881 of this title (relating to What curriculum components must be included in the general pre-service training?) Each caregiver would be required to receive a minimum of 16 hours of pre-service training in a course led by a qualified instructor. (See §748.863 of this title (relating to What are the pre-service hourly training requirements for caregivers and employees?) and §748.869 of this title (relating to What are the instructor requirements for providing pre-service training?)). It must be competency based and require participants to demonstrate competency upon completion. Each caregiver must complete a minimum of 20 hours of additional training annually, including specific training on EBI if it is used in the facility. (See §748.931 of this title (relating to What are the annual training requirements for caregivers and employees?)). Overall, the comments imply that licensure as a GRO would not change current practice in the FRC, a contention with which, as discussed above, DFPS disagrees.

Comment: Many commenters expressed concern over the risk of psychological harm for children and families residing in the centers. These commenters stated that the risk is particularly acute for immigrants, who have often fled persecution, abuse, and frequent trauma in their homelands. Commenters also asserted that children are especially at risk of developing short and long-term mental health issues due to being detained in the centers. One commenter specifically noted that infants living in detention centers have problems with brain development and social functioning due to disruptions in emotional attachments to their mothers, and children living in detention centers tend to have greater maladaptive social and emotional development, academic failure, and criminal involvement than children not living in detention centers. One commenter noted that the children know they are in detention centers and feel they are being punished, thereby, normalizing the concept of detention and negatively impacting their moral development and understanding of the criminal justice system. Further, commenters stated that many women and children in the centers are exhibiting symptoms of post-traumatic stress disorder, anxiety, depression, and

other mental illnesses, and are not receiving adequate treatment for these issues.

Response: While DFPS is sympathetic to the concerns raised, the agency has no role in whether a person is placed or detained in one of the FRCs. However, so long as children are housed there, and so long as mothers are not permitted to fully exercise their parental responsibility, DFPS considers the FRCs to be providing child care. It is more protective of the children in the FRCs for DFPS to exercise its oversight than to abdicate its responsibility based on the notion that the centers are harmful.

Comment: A number of commenters expressed concern that the living conditions in the centers fail to meet the basic needs of children and families and pose fundamental threats to their health and safety. Commenters' specific concerns included residents' inadequate access to healthy, regular meals and snacks; cold temperatures in the centers and residents' inadequate access to heating or blankets; close living quarters in the centers with a large number of unrelated individuals; unhygienic living conditions; other poor living conditions and inadequate access to education for minors in the centers.

Response: Living conditions, to the extent they are covered by CCL's Minimum Standards for GROs, would be addressed during the licensure process. To the extent the living conditions relate to be the practices of the federal government or its contractors with respect to adults in the FRCs, they are outside DFPS' scope of authority.

Comment: A significant number of commenters expressed concern that residents' health care needs are not being met in the Karnes County and Dilley centers. One commenter noted that the US Commission on Civil Rights found that the Karnes County center failed to comply with federal standards for medical care. Commenters asserted that specific problems at the centers include: failure to administer proper medical protocol; failure of medical staff to obtain informed consent of patients prior to medical treatment; unavailability of doctors when residents are ill; failure to timely treat residents' illnesses; failure to timely refer patients to hospitals when they are critically ill; administration of adult doses of vaccines to children; prescription of solely water or Vick's Vaporub to treat various illnesses, including serious illnesses; lack of follow-up care; unreasonably lengthy waiting times to receive care; and mothers being asked to sign waivers stating they have declined medical care if they leave the medical facility for any reason, despite long waiting times.

Response: DFPS' scope of authority is limited to the provision of medical care to children in the facility, and defers to the expertise of medical professionals in the determination of frequency and mode of treatment. However, Minimum Standards contain requirements specifically geared at ensuring a baseline of adequate medical treatment for children in care.

Generally speaking, an operation must provide medical and dental care to children in the operation. A child in care must receive medical and dental care: (1) initially, upon admission; (2) at as early an age as necessary; (3) as needed for relief of pain and infections (dental) or as needed for injury, illness, and pain (medical); and (4) as needed for ongoing maintenance of dental or medical health. See §748.1501 of this title (relating to What general dental requirements must my operation meet?) and §748.1531 of this title (relating to What general medical requirements must my operation meet?).

A licensed dentist must determine the need and frequency of ongoing maintenance of dental health. (See §748.1503 of this title

(relating to Who must determine the need and frequency of ongoing maintenance of dental health for a child?). A health-care professional must determine the need and frequency for ongoing maintenance of medical care and treatment for a child. (See §748.1533 of this title (relating to Who determines the need and frequency for ongoing maintenance of medical care and treatment for a child?)). The operation must comply with dentist and health-care professional recommendations for examinations and treatment for each child. (See §748.1501(d) and §748.1531(d) of this title). Subchapter J of this chapter (relating to Child Care) contains additional requirements related to various aspects of health care, including immunizations, communicable diseases, and nutrition and hydration, among others. Additional rights for children in care related to treatment are found in Subchapter H of this chapter (relating to Child Rights).

Comment: Several commenters expressed concerns related to issues with the staff at the centers. One commenter expressed concern about the ethical practices of the management of the Karnes County center after her experience as a social worker there. The commenter reported being repeatedly asked to omit written information about residents' mental health needs from reports, to lie to federal immigration officials, and to withhold information from residents about their rights within the center. Other commenters asserted that staff misconduct regarding abuse and sexual assault has not been adequately addressed. In addition, one commenter stated that the centers are not complying with the Prison Rape Elimination Act (PREA) solitary confinement practices, which require that solitary confinement of minors to keep them or other residents safe only be used as a last resort. A few commenters noted that not only are the centers understaffed, but the employees are not qualified or trained to serve the families.

Response: Some of the concerns are outside DFPS' scope, such as extent of compliance with PREA. However, CCL will be implementing and enforcing Minimum Standards that would address some of the concerns regarding staff, at least insofar as they are serving in the role as a caregiver to a child. As previously discussed, Minimum Standards contain relatively extensive training requirements for all caregivers. For any facility that utilizes EBI, the training must include current information on EBI, and DFPS regulations generally require de-escalation and other age-appropriate techniques prior to utilization of any more severe measures. DFPS could not monitor staffing as a general proposition, but would monitor the adequacy of staff for the purposes of child-to-caregiver ratios in place in the FRCs. Minimum Standards also require various measures related to personnel and record keeping. In particular a permit holder must ensure the reporting of serious incidents including suspected abuse, neglect and exploitation. (See §748.105 of this title (relating to What are my operational responsibilities as the permit holder?)). Record keeping must ensure accurate and current child records. (See §748.393 of this title (relating to How must I maintain an active child record?)).

Comment: Several commenters advised that DFPS should take heed and not partake in the historical repetition of using family detention centers that inflict harm upon children and families. Commenters described how the T. Don Hutto Family Detention Center, ICE's first detention center in Texas that opened in 2006 and was operated by the for-profit corporation CCA, became a national and international scandal due to its substandard living quarters, inadequate health care, and inhumane treatment of children. Commenters noted that the American Civil Liberties Union of Texas (ACLU) and the University of Texas Immigration

Law Clinic successfully sued ICE to stop the use of the center for the detention of immigrant children and families.

Response: DFPS does not influence whether a family or child is placed in an FRC; rather, DFPS is carrying out its duty "to protect the health, safety, and well-being of the children of the state who reside in child-care facilities by establishing statewide minimum standards for their safety and protection and by regulating the facilities through a licensing program" for those children who are placed in the FRC. (See HRC §42.001).

(4) Comments Relating to DFPS' Authority to Investigate Abuse and Neglect Allegations in the Facilities Without Licensure:

Comment: Several commenters opposed licensure, stating that DFPS has statutory authority to investigate abuse and neglect in non-licensed FRCs, and therefore, can already provide regular and comprehensive oversight of the centers without licensure. The commenters stated that DFPS offers no explanation of how licensing and exempting the FRCs from minimum child-care standards will protect the children from abuse and neglect. Furthermore, the commenters asserted that creating exemptions will weaken DFPS' ability to ensure child safety and well-being. One commenter suggested that rather than licensing the FRCs, DFPS should instead appoint an independent medical and psychological team to investigate reports of abuse, neglect, and exploitation in order to monitor and assure the well-being of the detained children.

Response: DFPS has consistently maintained that CPS could investigate reports of abuse or neglect by a parent or caretaker in the FRCs. Conducting abuse or neglect investigations, however, is only one part of regulation. A child abuse or neglect investigation conducted by childcare licensing should be conducted within the scope of the operation's effort to comply with relevant minimum standards.

Significantly, for the purposes of child protection, licensure offers an ongoing avenue to monitor medical care as well as allegations of abuse and neglect and other deficiencies in FRCs. While the commenters were concerned that the only additional authority in the licensure would be to inspect specific licensing requirements, this is in truth a significant enhancement, as detailed herein, and invokes a comprehensive regulatory and protective scheme. Responding to reports of abuse and neglect is reactive, and it assumes that a vulnerable individual has access to a telephone or the Internet to freely make the report. Licensure is comprehensive, ongoing, and gives DFPS the authority to make both announced and unannounced inspections, in addition to investigating individual reports of abuse or neglect. If a staff member is found to have abused or neglected a child there could be implications to the staff member's ability to work in the operation, which would not occur if the facility were not subject to regulation as a child-care facility, specifically as a GRO.

Finally, DFPS lacks authority to appoint an independent medical and psychological team to investigate reports of abuse, neglect and exploitation. The agency itself has the authority to investigate, but cannot without additional statutory authority and resources abdicate this responsibility and grant it instead to an independent group of medical and psychological professionals.

(5) Comments Relating to the Flores Settlement:

Comment: Many commenters argued that placing children in the Dilley and Karnes County centers violates the Flores settlement, which provides that children in immigration custody be placed in the least restrictive setting appropriate to their age and special

needs, generally, a non-secure FRC licensed to care for dependent, as opposed to delinquent, minors. Commenters argued that the prison-like environments of the FRCs violate Flores, and licensing the FRCs with various exceptions will not remedy the violation. One commenter was concerned that the potential licensure of the two FRCs would permit ICE and its private partners to attempt to claim compliance with Judge Gee's July 24, 2015, and August 21, 2015, orders. One commenter noted that the U.S. Commission on Civil Rights conducted an extensive investigation into the FRCs and found that the Department of Homeland Security and its contractors are not holding children in the least restrictive settings. Additionally, one commenter asserted detention is unnecessary because the majority of the families at the FRCs have already demonstrated credible fear to an asylum officer, do not pose a threat to public safety, and have relatives in the United States to house them while they await a hearing.

Response: DFPS has repeatedly emphasized that its role with respect to the two FRCs currently in Texas is to oversee the care of the children who are housed with their mothers or family members there, not to determine whether the facility is secure. DFPS has no control over whether individuals are placed in the FRCs, and any outcome in the litigation is a matter outside the scope of DFPS' purview.

(6) Comment Concerning DFPS' Overall Authority to License the FRCs:

Comment: One commenter argued that DFPS' regulation of FRCs was unlawful and without authority because the FRCs violate state laws regarding the detention of juveniles. The commenter argued that the Texas Family Code offers a "robust series of statutes that specifically prohibit, and even criminalize placement of certain children in secure detention facilities." The commenter documented reasons why the FRCs should be considered secure detention facilities, including the use of techniques such as isolation as punishment, the existence of high walls, restrictions on movement, and so forth. The commenter then argued that because they are secure detention facilities where children are held, the FRCs, and any licensure of those FRCs, violates Texas laws regarding juvenile offenders. Specifically, the commenter asserts both that DFPS lacks statutory authority for and that DFPS is explicitly banned from licensure of the FRCs, though for the latter point no particular authority is cited. The rule, per the commenter, is without legal authority because children in the FRCs may be detained beyond statutory time frames and in contravention of other restrictions in Chapter 51 of the Texas Family Code (TFC), and because the children are never adjudicated in front of a Texas juvenile court but are being housed to enforce deportation laws, in contravention of TFC §54.011(f). Further, the commenter suggested that DFPS' licensure effectively aids in the commission of a Class B misdemeanor under the same statutory provision of TFC §54.011. The commenter explained that Texas juvenile detention laws prohibit the secure detention of children under the age of ten. Finally, after arguing that DFPS has no authority to regulate the centers as child-care facilities, the commenter concluded that DFPS was obligated to immediately order the FRCs to cease operation because they have been operating without such a license for more than one year pursuant to CCL's enabling chapter.

Response: The commenter's arguments related to the TFC are misplaced. As noted in materials attached by the commenter, the chapters of the TFC in question relate to facilities operated

by or on behalf of the Texas Juvenile Justice Department or on behalf of a juvenile board in the state of Texas. They do not govern federal facilities, including the FRCs under discussion in this rule promulgation. To the commenter's point that DFPS should immediately order the FRCs to cease operation as unlicensed facilities, DFPS has not previously issued regulatory guidance regarding the FRCs' status and to take enforcement action against the operators of the FRCs would in all likelihood violate the Administrative Procedure Act, Chapter 2001 of the Texas Government Code, in addition to being patently unjust. DFPS declines to take any such action on the basis of a previously nonexistent regulatory pronouncement.

(7) Comments Relating to the Proposed Rule Being Contrary to DFPS' mission:

Comment: A significant number of commenters argued that the proposed rule is at odds with DFPS' mission to protect children and families from abuse, neglect, and exploitation. These commenters expressed concern over the FRCs' ability to provide for the safety and well-being of children when the FRCs were created to detain immigrants under federal immigration law and are managed by privately-owned prison companies under contract with ICE. A few commenters called DFPS' integrity into question, asserting that the decision to license these FRCs is not motivated by concern for the children because licensing would not address or solve the problem of family detention. Specifically, one commenter argued that the rule does not have the best interests of children in mind, but rather exists only because these FRCs were determined to be outside of compliance by the court system. Additionally, many commenters argued that if DFPS truly wanted to hold these FRCs accountable for the well-being of children, DFPS would have responded to the numerous complaints received and investigated the FRCs under current authority.

Response: DFPS has concluded that licensure of the FRCs is mandated and consistent with its mission to protect vulnerable children in care. DFPS views the licensure process as a tool to enhance the FRCs' ability to provide for the children's safety and well-being. DFPS seeks not to solve the problem of family detention, but rather to provide protective oversight for children who find themselves in the FRCs. Finally, based on careful and ongoing review of the issues over the course of time, DFPS' position has evolved and culminated in the regulatory action contained herein.

(8) Comments Relating to the Fiscal Implications of the Proposed Rule:

Comment: A few commenters noted that the Child Care Licensing Division of DFPS already has limited resources so licensing two large facilities would have negative fiscal implications and involve a drain on other crucial agency resources. One commenter expressed concern over DFPS' estimate that the rule will have no fiscal impact upon the agency, questioning how DFPS would provide the essential protection of regular and comprehensive oversight to the centers without a budget. Additionally, the commenter expressed concern for the lack of budget line items for psychiatrists, psychologists, or counselors in the private operators' budget of \$32 million a year for both centers. Additionally, a few commenters noted that there are other established alternatives that could address the government's legitimate interests in managing immigration and ensuring child safety without inflicting further trauma on the families and at a lower financial cost.

Response: DFPS has concluded that it can absorb the workload associated with the rule within current resources, at least during the first five years following the rule's effective date. One of the FRCs submitted commentary that DFPS' fiscal estimates were too low, as discussed herein. DFPS believes its estimates are sound. Ultimately, the FRCs will assess the true costs of compliance to them and engage in the requisite cost-benefit balance analysis to determine how to proceed. Alternatives to the federal government's current immigration practice are outside the scope of this rule and DFPS' authority.

(9) Comments Relating to the Berks County Residential Center in Leesport, Pennsylvania:

Comment: Two commenters noted that the Pennsylvania Department of Human Services has publicly stated that it will refuse to renew the license of Berks County Residential Center, an ICE family detention center in Pennsylvania housing immigrant children and families similar to the Karnes County and Dilley centers, if the practice of using the facility as a secure family detention center continues because such practice is inconsistent with its current license as a child residential facility. The commenters urged DFPS to follow suit and refuse to license the Karnes County and Dilley centers.

Response: DFPS respects Pennsylvania's interpretation of its licensing laws and regulations. For the purposes of Texas law, DFPS has determined that the oversight inherent in licensure better serves the aims of child protection than the lack thereof.

(10) Comments Relating to the City of Dilley's Lack of Infrastructure to Support the Dilley Center:

Comment: One commenter opposed the rule, not due to the rule itself, but because the city of Dilley, with a population of only 3,894 residents, does not possess the infrastructure to support a large detention center. The commenter noted that water has cut out several times for the entire city since the Dilley center opened, and the center has had to call the city's emergency services for other unrelated incidents rather than being able to resolve such issues internally.

Response: DFPS would make basic assessments regarding the physical site as part of the licensure process. An assessment of the city's infrastructure would be beyond DFPS' authority, which would focus on the adequacy of the facility and its utilities vis-à-vis the provision of child care.

(11) Comments of Reasons for Adoption:

Comment: DFPS received two requests for a written, detailed rationale of the reasons for its adoption, or non-adoption, of the rule in question.

Response: While no particular authority was cited, DFPS will err on the side of maximum transparency and construe the requests to be requests for a statement of reasons for or against adoption pursuant to Texas Government Code §2001.030. Again, in the interest of maximum transparency, DFPS will include the statement in this preamble, though such inclusion is not required by the Government Code.

The principal reasons urged against the adoption of the rule may be summarized by reference to themes 2-10 detailed in the comments and response section. DFPS' reasoning for overruling the considerations and adopting the rule is discussed in detail in the summary section as well. It may be summarized by reiterating that the agency has concluded the broad regulatory scheme in

place for GROs will be more protective of children than taking no action regarding the provision of child care without a license.

Section 748.7 is being adopted with change. DFPS staff made modifications to subsection (c), paragraphs (1), (2), (3), and subsection (d) to clarify the extent of and reasons for the variances.

The new section is adopted under §40.0505, Human Resources Code, and §531.0055, Government Code, which provide that the Health and Human Services Executive Commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including the Department of Family and Protective Services.

The new section implements §42.042(a), Human Resources Code.

§748.7. *How are these regulations applied to family residential centers?*

(a) Definition. A family residential center is one that meets all of the following requirements:

(1) The center is operated by or under a contract with United States Immigration and Customs Enforcement;

(2) The center is operated to enforce federal immigration laws;

(3) Each child at the center is detained with a parent or other adult family member, who remains with the child at the center; and

(4) A parent or family member with a child provides the direct care for the child except for specific circumstances when the child is cared for directly by the center or another adult in the custody of the center.

(b) Classification. A family residential center is a general residential operation (GRO) and must comply with all associated requirements for GROs, unless the family residential center is approved for an individual waiver or variance or an exception is provided in this section. The department is responsible for regulating the provision of childcare as authorized by Chapters 40 and 42, Texas Human Resources Code and Chapter 261, Texas Human Resources Code. The department does not oversee requirements that pertain to other law, including whether the facilities are classified as secure or in compliance with any operable settlement agreements or other state or federal restrictions.

(c) Exceptions. A family residential center is not required to comply with all terms of the following Minimum Standards:

(1) the limitation of room occupants to four in §748.3357 of this title (relating to What are the requirements for floor space in a bedroom used by a child?), except that nothing in this exception shall be construed to require fewer than 60 square feet per child;

(2) the limitation on a child sharing a bedroom with an adult in §748.3361 of this title (relating to May a child in care share a bedroom with an adult?), if the bedroom is being shared in order to allow a child to remain with the child's parent or other family member; and

(3) the limitations on children of the opposite gender sharing a room in §748.3363 of this title (relating to May children of opposite genders share a bedroom?), except that nothing in this exception shall be construed to permit children from different families who are over the age of six and members of the opposite gender to share a bedroom.

(d) Limitation of exception. Notwithstanding subsection (c) of this section, and as further described in §745.8313 of this title (relating to Is a waiver or variance unconditional?), the department retains the authority for placing conditions on the scope of the exceptions authorized for a family residential center, including conditions related to limiting occupancy in accordance with fire safety standards, limitations related to allowing children and adults of the opposite gender to occupy the same room only if they are part of the same family, and any other limitation determined by the department to be necessary to the health, safety, or welfare of children in care.

(e) Division of responsibility. In addition to the application materials described in §745.243(6) of this title (relating to What does a completed application for a permit include?), an applicant for a license under this section must submit the policies, procedures, and any other documentation that the department deems necessary to clarify the division of supervisory and caretaking responsibility between employees of the facility and the parents and other adult family members who are housed with the children. The department must approve the documentation during the application process and any subsequent amendments to the policies and procedures.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Trevor Woodruff

General Counsel

Department of Family and Protective Services

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For further information, please call: (512) 438-3854

