

The Texas Commission on Environmental Quality (TCEQ, agency or commission) adopts the amendment to §281.19. Section 281.19 is adopted *without change* to the proposed text as published in the September 7, 2007, issue of the *Texas Register* (32 TexReg 6056) and will not be republished.

BACKGROUND AND SUMMARY OF THE FACTUAL BASIS FOR THE ADOPTED RULE

The purpose of this rulemaking is to implement Senate Bill (SB) 1604, 80th Legislature, 2007, and its amendments to Texas Health and Safety Code (THSC), Chapter 401 (also known as the Texas Radiation Control Act (TRCA)). The bill transfers responsibilities for the regulation and licensing of source material recovery, by-product disposal, and commercial radioactive substances storage and processing from the Texas Department of State Health Services (department) to the commission. This rulemaking intends to transfer the technical requirements for these programs from the department's rules in 25 TAC §289.254 and §289.260 into new subchapters of the commission's radioactive substance rules in Chapter 336.

While the technical requirements remain the same, these new commission programs will be integrated into and administered under the commission's existing radioactive material program requirements for application processing, public notice, public participation, licensing fees, and enforcement. The amendments to Chapter 281, Subchapter A establish the procedural requirements for the technical review of radioactive material licenses under Chapter 336.

SB 1604 also establishes a new state fee for disposal of radioactive substances and amends underground injection control requirements for uranium mining. The commission intends to address the new requirements in separate rulemaking actions.

A corresponding rulemaking is published in this issue of the *Texas Register* and includes changes to 30 TAC Chapter 39, Public Notice; and Chapter 336, Radioactive Substance Rules.

SECTION DISCUSSION

The commission adopts administrative changes throughout this section to be consistent with *Texas Register* requirements and other agency rules and guidelines and to conform to the drafting standards in the *Texas Legislative Council Drafting Manual*, August 2006.

The commission adopts the amendment to §281.19(a) to correct outdated cross-references.

The commission adopts the amendment to §281.19(a) and (c) to extend the maximum period for conducting the technical review of radioactive material license applications from 450 days to 600 days and to increase the maximum number of notice of deficiencies that can be submitted by the executive director in the review of a license application from two to four. The longer review period and additional rounds of executive director comment on applications will greatly improve the quality of applications submitted to the agency and, thus, the quality and protectiveness of licenses issued by the commission. Applications for radioactive material licenses are complex and require the collection of a great deal of information that is unique to a proposed location. The additional time for conducting the technical review allows an applicant sufficient time to provide all required information to the executive director. The commission also adopts the amendment to allow the executive director to extend or delay the schedule under this subsection to comply with the priority given to the review and processing of applications pursuant to TRCA, §401.237(c) and Section 34(b) and (c) of SB 1604. The commission intends that the changes to this subsection apply only to applications submitted after the effective date of this rule change.

The commission adopts the amendment to §281.19(d) to address the applications for licenses that were pending with the department prior to transfer of agency responsibilities established under SB 1604. The applications that are pending at the department will be subjected to a maximum technical review period of 600 days at the commission with a maximum of two notices of deficiency issued by the executive director. The processing of these pending applications is subject to the priority for the review and processing of radioactive material licenses in TRCA, §401.237(c) and Section 34(b) and (c) of SB 1604.

FINAL REGULATORY IMPACT ANALYSIS DETERMINATION

The commission adopts the rulemaking action under the regulatory analysis requirements of Texas Government Code, §2001.0225, and determined that the action is not subject to §2001.0225 because it does not meet the definition of "A major environmental rule" as defined in the statute. "A Major environmental rule" means a rule, the specific intent of which, is to protect the environment or reduce risks to human health from environmental exposure and that may adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state. The amendment to Chapter 281 is procedural, establishing the requirements for the processing of a license application. The amendment to Chapter 281 is not anticipated to adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state, because the amendment establishes procedural requirements for radioactive substance disposal facilities, source material recovery facilities, or commercial radioactive substances storage and processing facilities. The rulemaking action implements legislative requirements in SB 1604, transferring responsibilities for the regulation of source material recovery, by-product disposal, and commercial radioactive substances storage and processing from the department to the commission. The rulemaking in Chapter 336 transfers

the technical requirements for these licensing programs from the department's existing rules to the commission's rules. The rulemaking also integrates the transferring license programs into existing commission procedural requirements in Chapters 39 and 281.

Furthermore, the rulemaking action does not meet any of the four applicability requirements listed in Texas Government Code, §2001.0225(a). Texas Government Code, §2001.0225 only applies to a major environmental rule, the result of which is to: 1) exceed a standard set by federal law, unless the rule is specifically required by state law; 2) exceed an express requirement of state law, unless the rule is specifically required by federal law; 3) exceed a requirement of a delegation agreement or contract between the state and an agency or representative of the federal government to implement a state and federal program; or 4) adopt a rule solely under the general powers of the agency instead of under a specific state law.

The rulemaking action does not exceed a standard set by federal law, an express requirement of state law, a requirement of a delegation agreement, nor does it adopt a rule solely under the general powers of the agency. Texas Health and Safety Code, Chapter 401, authorizes the commission to regulate the disposal of most radioactive substances in Texas. Texas Health and Safety Code, §§401.051, 401.103, 401.104, and 401.412 authorize the commission to adopt rules for the control of sources of radiation and the licensing of the disposal of radioactive substances. In addition, the State of Texas is an "Agreement State" authorized by the United States Nuclear Regulatory Commission (NRC) to administer a radiation control program under the Atomic Energy Act of 1954, as amended (Atomic Energy Act). The rulemaking is compatible with federal law.

The rulemaking does not exceed an express requirement of state law. Texas Health and Safety Code, Chapter 401, establishes general requirements for the licensing and disposal of radioactive substances, source material recovery, and commercial radioactive substances storage and processing. The purpose of the rulemaking is to implement statutory requirements consistent with recent amendments to Texas Health and Safety Code, Chapter 401, as provided in SB 1604.

The rulemaking is compatible with a requirement of a delegation agreement or contract between the state and an agency of the federal government. The State of Texas has been designated as an "Agreement State" by the NRC under the authority of the Atomic Energy Act. The Atomic Energy Act requires that the NRC find that the state radiation control program is compatible with the NRC requirements for the regulation of radioactive materials and is adequate to protect health and safety. Under the *Agreement Between the United States Nuclear Regulatory Commission and the State of Texas for Discontinuance of Certain Commission Regulatory Authority and Responsibility Within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended*, NRC requirements must be implemented to maintain a compatible state program for protection against hazards of radiation. The rulemaking is compatible with the NRC requirements and the requirements for retaining status as an "Agreement State."

The rulemaking is adopted under specific authority of the Texas Health and Safety Code, Chapter 401. Texas Health and Safety Code, §§401.051, 401.103, 401.104, and 401.412 authorize the commission to adopt rules for the control of sources of radiation and the licensing of the disposal of radioactive substances.

The commission invited public comment of the draft regulatory impact analysis determination. No comments were received on the draft regulatory impact analysis determination.

TAKINGS IMPACT ASSESSMENT

The commission evaluated the rulemaking and performed an assessment of whether Texas Government Code, Chapter 2007 is applicable. The commission's assessment indicates that Texas Government Code, Chapter 2007 does not apply to the rulemaking. The rulemaking implements SB 1604, transferring certain regulatory responsibilities for the control of radioactive material from the department to the commission. This rulemaking is reasonably taken to fulfill an obligation required by federal law for the control of radioactive material, which is an exempt action under Texas Government Code, §2007.003(b)(4).

Nevertheless, the commission further evaluated the rulemaking and performed an assessment of whether the rule constitutes a taking under Texas Government Code, Chapter 2007. The purpose of this rulemaking is to implement changes to the Texas Radiation Control Act required by SB 1604, 80th Legislature, 2007 for the processing of applications for a license for the disposal of radioactive substances, recovery of source material, and commercial radioactive substances processing and storage. The rulemaking would substantially advance this purpose by establishing the technical review period for license applications subject to the commission's jurisdiction under the TRCA as amended by SB 1604.

Promulgation and enforcement of the rulemaking would be neither a statutory nor a constitutional taking of private real property. The rulemaking does not affect a landowner's rights in private real property because this rulemaking action does not constitutionally burden, nor restrict or limit, the owner's right to property and reduce its value by 25% or more beyond which would otherwise exist in the absence of the

regulations. The rulemaking establishes application processing requirements and does not affect real property. The rulemaking does not change the existing technical requirements that were in place under the department's program. Therefore, the commission's rulemaking does not affect real property in a manner that is different than may have been affected under the department's requirements.

CONSISTENCY WITH THE COASTAL MANAGEMENT PROGRAM

The commission reviewed the rulemaking and determined that the rulemaking is neither identified in, nor will it affect, any action/authorization identified in Coastal Coordination Act Implementation Rules in 31 TAC §505.11, relating to Actions and Rules Subject to the Texas Coastal Management Program (CMP). Therefore, the rulemaking action is not subject to the CMP.

PUBLIC COMMENT

The commission held a public hearing on September 25, 2007. The comment period closed on October 15, 2007. Comments were received from Mesteña Uranium, L.L.C. (Mesteña); the Lone Star Chapter of the Sierra Club (Sierra Club); the Uranium Committee of the Texas Mining and Reclamation Association (TMRA); Kelly Hart & Hallman LLP on behalf of Uranium Energy Corp., AREVA NC, Inc., and Uranerz Energy Corporation (UAU); Hance Scarborough Wright Woodward & Weisbart on behalf of Waste Control Specialists LLC (WCS); and the Texas Radiation Advisory Board (TRAB). Mesteña supports the revisions as necessary for the orderly and complete program transfer of the radioactive materials programs that oversee uranium recovery operations. The Sierra Club commented that the Sierra Club is pleased with the proposed rule overall and that the proposed rule adequately implements the statutory changes made by SB 1604. TMRA commented on its appreciation of the time and effort the TCEQ has put forth as part of the rulemaking process. Specific comments are addressed below.

RESPONSE TO COMMENTS

General Comments on Applications Processing

The Sierra Club commented that the commission's proposal preamble incorrectly stated that changes to §281.19(a) apply after the effective date of the rule change because SB 1604 was effective upon passage.

The commission disagrees with the comment. While SB 1604 was effective upon passage, the terms of SB 1604 in Section 33(d) require the application of the department's rules until the commission adopts other rules. No changes were made in response to the comment.

Mesteña recommends that the commission develop regulatory guidance to assist in the development of an application.

The commission agrees with the comment and intends to develop regulatory guidance and application forms that will enhance the quality of applications submitted and should reduce the amount of time required for preparation, revision, and review of a license application. No changes were made in response to the comment.

Technical Review

The Sierra Club supports the rule change to allow more time to review an application in certain cases. UAU expressed appreciation for the commission's attempt to recognize the complexity of radioactive material licenses by providing an extended review period. WCS expressed agreement with the extension of time to conduct the technical review. Mesteña and TMRA commented that §281.19(a) increases the length of time for the technical review of a license application that was available under the department's

rules. TMRA seeks understanding on how the commission could determine that there will be no adverse fiscal impacts to businesses by the increase of the technical review period up to 600 days. TMRA requests the commission to clarify if the intent of the extension is to help keep applications within the review process rather than being returned to the applicant.

The commission appreciates the comments. The commission has determined that applications for radioactive material license can be quite complex and require the generation of site-specific data and studies. Therefore, the increase in the maximum amount of time allowed for completing the technical review from 450 days to 600 days for radioactive material licenses is warranted. The commission does not agree that this is an increase from department requirements for completing the technical review. Under the department rules in 25 TAC §289.252, the technical review period can be unlimited. The review period at the commission is not unlimited and deficient applications may be returned to the applicant. Under the rules adopted by the commission, every applicant has the ability to minimize the amount of time required to complete the technical review by submitting a high-quality application. The technical review period will not exceed 255 days, but the period may be extended only if the application is technically deficient. Such an extension is not intended to help nor hinder an applicant, but is made in recognition of the complexity of the subject matter and the amount of information that needs to be submitted in the application. The commission does not agree that an applicant will be affected financially by the lengthening of the maximum review period because an applicant controls the length of the review period by submitting quality application materials. And, the technical review of license applications at the commission is not an indefinite process. No changes were made in response to these comments.

UAU expressed appreciation for the commission's attempt to recognize the complexity of radioactive material licenses by providing an opportunity for additional Notices of Deficiency. WCS expressed support for additional opportunities of Notices of Deficiency and recommends that §281.19(d) should also be modified to allow four Notices of Deficiency on applications that were pending at the department on the effective date of SB 1604, providing the same number of rounds of review as afforded new applications. The Sierra Club does not support the change to allow four Notices of Deficiency rather than two, because: such a process would allow applicants to submit weak applications in hopes that commission staff will not catch omissions or that staff will perform work for the applicant; the allowance of four Notices of Deficiency is unfair to applicants who submit good applications, and; it will add work and costs to the TCEQ. TMRA requests the commission to clarify if the intent of the increase in the number of Notices of Deficiency is to help keep applications within the review process rather than being returned to the applicant.

The commission appreciates the comments. Because of the complexity and amount of information required in license applications, additional rounds of technical review provided in the notice of deficiency process are warranted up to a maximum of four notices for a new application. These additional rounds are not intended to help or hinder the applicant, but are provided to assure a thorough review of the application. The increase in the number of notices is not provided so that TCEQ staff will perform the applicant's work. TCEQ staff are not authorized to perform the applicant's work. The commission does not agree that the rule change will affect the agency's costs because application fees cover the agency's costs for review of the applications. The commission disagrees with the comment that recommends that applications that were pending at the department on the effective date of SB 1604 be subjected to a maximum of four notices of

deficiency. Under Section 33(d) of SB 1604, the commission is required to continue a proceeding of the department including the processing of an application for a license. Subjecting these pending applications to the same process for new applications, would ignore the progress made on the review of pending applications since the time the applications were submitted to the department.

No changes were made in response to these comments.

SUBCHAPTER A: APPLICATIONS PROCESSING

§281.19

STATUTORY AUTHORITY

The amendment is adopted under Texas Water Code, §5.103, concerning Rules, and §5.105, concerning General Policy, which authorize the commission to adopt rules necessary to carry out its powers and duties under the Texas Water Code and other laws of the state. The amendment is also adopted under Texas Health and Safety Code, Chapter 401, concerning Radioactive Materials and Other Sources of Radiation (also known as the Texas Radiation Control Act); §401.011, concerning Radiation Control Agency, which authorizes the commission to regulate and license the disposal of radioactive substances, the processing or storage of low-level radioactive waste or naturally occurring radioactive material, the recovery or processing of source material, and the processing of by-product material; §401.051, concerning Adoption of Rules and Guidelines, which authorizes the commission to adopt rules and guidelines relating to control of sources of radiation; §401.103, concerning Rules and Guidelines for Licensing and Registration, which authorizes the commission to adopt rules and guidelines that provide for licensing and registration for the control of sources of radiation; §401.104, concerning Licensing and Registration rules, which requires the commission to provide rules for licensing for the disposal of radioactive substances; §401.202, concerning Regulation of Low-Level Radioactive Waste Disposal, which authorizes the commission to regulate commercial processing and disposal of low-level radioactive waste; §401.262, concerning Management of Certain By-Product Material, which provides the commission authority to regulate by-product storage and processing facilities; and §401.412, concerning Commission Licensing Authority, which authorizes the commission to issue licenses for the disposal of radioactive substances.

The adopted amendment implements Texas Health and Safety Code, as amended by SB 1604, 80th Legislature, 2007, §§401.011, 401.051, 401.103, 401.104, 401.151, 401.202, 401.262, 401.2625, and 401.412.

§281.19. Technical Review.

(a) After an application is determined by the executive director to be administratively complete, the executive director shall commence a technical review as necessary and appropriate. For purposes of these sections, the technical review period is that period of time beginning with the completion of the initial review period and will continue for a period of time not to exceed 75 working days. In the case of applications filed under §291.102 of this title (relating to Criteria for Considering and Granting Certificates or Amendments), the technical review period is that period of time beginning 30 days after notice of the application has been given in accordance with §291.109 of this title (relating to Report of Sale, Merger, etc.; Investigation; Disallowance of Transaction) and will continue for a period of time not to exceed 75 working days. In the case of applications filed under §335.43 of this title (relating to Permit Required) or §331.7 of this title (relating to Permit Required), the technical review period shall commence upon assignment of the application to a staff member and continue for a period of time not to exceed 120 days. For applications filed under Chapter 336 of this title (relating to Radioactive Substance Rules) and subject to the Notice of Deficiency (NOD) process established in this section, the technical review period shall begin the day after the date of determination of administrative completeness and for issuance, renewal, or major amendments, shall continue for a period of time not to exceed 255 days; however, this time frame may be extended to a maximum of 600 days if an application is technically

deficient; or, for applications for minor amendments, shall continue for a period of time not to exceed 90 days; however, this time frame may be extended to a maximum of 150 days if an application is technically deficient.

(b) Except as provided in subsection (c) of this section, the applicant shall be promptly notified of any additional technical material as may be necessary for a complete review. If the applicant provides the information within the period of time prescribed by subsection (a) of this section, the executive director will complete processing of the application within the technical review period extended by the number of days required for the additional data. If the necessary additional information is not received by the executive director prior to expiration of the technical review period and the information is considered essential by the executive director to make recommendations to the commission on a particular matter, the executive director may return the application to the applicant. In no event, however, will the applicant have less than 30 days to provide the technical data before an application is returned. Decisions to return material to the applicant during the technical review stage will be made on a case by case basis. The applicant has the option of having the question of sufficiency of necessary technical data referred to the commission for a decision instead of having the application returned.

(c) For applications for radioactive material licenses, the applicant shall be promptly notified of any additional technical information necessary to complete technical review. For new applications, renewal applications, or major amendment applications, the executive director shall complete application processing within the technical review period (600 days) if the applicant provides the information within 75 days of the date of the first NOD and 60 days of the subsequent NODs. For minor amendments, the applicant must provide the information within 20 days from the date of the first NOD and 20 days from

the date of the second NOD. If the necessary additional information is not received by the executive director prior to the end of the response period, the executive director may return the application to the applicant. In no instance shall the executive director issue more than four NODs before returning the application. The applicant has the option of having the question of sufficiency of necessary technical information referred to the commission for a decision instead of having the application returned. The applicant may request additional time to respond to a notice of technical deficiency. The request must be in writing, set forth the reasons why the applicant cannot respond within the time provided and specify the amount of additional time requested. Any extension of time must be approved by the executive director in writing. The executive director may extend or delay the schedule for the processing of an application under this subsection to comply with the priority established by law for processing and review of radioactive material licenses.

(d) This subsection applies to the technical review of applications for radioactive material licenses submitted to the Texas Department of State Health Services on or before June 18, 2007. For new applications, renewal applications, or major amendment applications, the executive director shall complete application processing within the technical review period (600 days) if the applicant provides the information within 75 days of the date of the first NOD and 60 days of the second NOD. For minor amendments, the applicant must provide the information within 20 days from the date of the first NOD and 20 days from the date of the second NOD. If the necessary additional information is not received by the executive director prior to the end of the response period, the executive director may return the application to the applicant. In no instance shall the executive director issue more than two NODs before returning the application. The applicant has the option of having the question of sufficiency of necessary technical information referred to the commission for a decision instead of having the application returned.

The applicant may request additional time to respond to a notice of technical deficiency. The request must be in writing, set forth the reasons why the applicant cannot respond within the time provided and specify the amount of additional time requested. Any extension of time must be approved by the executive director in writing. The executive director may extend or delay the schedule for the processing of an application under this subsection to comply with the priority established by law for processing and review of radioactive material licenses.