

soon as practicable but no later than August 31, 1990.

This agency hereby certifies that the rule as adopted has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued in Austin, Texas, on January 26, 1990.

TRD-9000962 Allen Ell Bell  
Executive Director  
Texas Air Control Board

Effective date: February 19, 1990

Proposal publication date: July 28, 1989

For further information, please call: (512) 451-5711, ext.354

## Pharmaceutical Manufacturing Facilities

### • 31 TAC §§115.531-115.537, 115.539

The Texas Air Control Board (TACB) adopts new §§115.531-115.537 and 115.539. Sections 115.535 and 115.539 are adopted with changes in the proposed text as published in the July 28, 1989, issue of the *Texas Register* (14 TexReg 3674). Sections 115.531-115.534, 115.536, and 115.537 are adopted without changes and will not be republished.

The new §115.531, concerning emission specifications, establishes the maximum level of acceptable emissions from specified sources. The new §115.532, concerning control requirements, defines the type of control or technologies required to achieve necessary emission reductions. The new §115.533, concerning alternate control requirements, enables the TACB executive director to approve substantially equivalent control technologies under specific conditions. The new §115.534, concerning inspection requirements, identifies the components needing inspection and the frequency they are to be inspected. The new §115.535, concerning testing requirements, identifies the test methods which must be used to determine compliance and enables the TACB executive director to approve minor modifications to the methods. The new §115.536, concerning recordkeeping requirements, describes the information which must be maintained by affected facilities in order to ensure continuous compliance and improve the effectiveness of enforcement. The new §115.537, concerning exemptions, specifies the conditions necessary to qualify for exemption from certain control requirements. The new §115.539, concerning counties and compliance schedules, establishes the final compliance dates for applicable controls in specified counties. These sections are part of a series of additions to Chapter 115 proposed primarily to satisfy United States Environmental Protection Agency (EPA) requirements for Phase I of the Post-1987 State Implementation Plan (SIP) revisions for ozone. The TACB also has adopted a comprehensive restructuring of Chapter 115 to promote greater clarity and to eliminate inconsistencies resulting from numerous independent revisions over the past several years.

The Administrative Procedure and Texas Register Act, Texas Civil Statutes, Article 6252-13a, §5(c)(1), requires categorization of comments as being for or against a proposal. A commenter who suggested any changes in the proposal is categorized as against the proposal; a commenter who agreed with the proposal in its entirety is classified as being for the proposal. Three commenters opposed the proposal, while no one testified in support.

One individual suggested controls and inspection requirements for loading and unloading emissions from ships and barges be required for pharmaceutical manufacturing facilities. TACB review of all affected sources has shown that no loading or unloading from ships and barges currently exists at any pharmaceutical manufacturing facility in Texas.

One individual also suggested applying control requirements for storage, vent gas streams, and loading operations consistent with other applicable sections of Regulation V. Generic controls regarding storage facilities, vent gas streams, and loading operations apply to all sources regardless of other control requirements for specific source categories.

Two commenters, the Sierra Club and one individual suggested a 500 gallon exemption instead of the proposed 2,000 gallon exemption for storage tanks at loading facilities. The individual also suggested the vapor pressure limits for exemptions for all storage facilities be lowered to 0.5 pounds per square inch absolute. These additional control options will be studied in the future and may be considered in subsequent rulemaking, if appropriate.

Two commenters, the United States Environmental Protection Agency (EPA) and one individual opposed the proposed general 550 pounds per day (lb/day) exemption for pharmaceutical manufacturing facilities. EPA suggested adoption of a 15 lb/day exemption consistent with the exemption level in Harris County. When controls for pharmaceutical sources covered by the control technique guideline were implemented, they were intended to apply only to major sources which are set at 100 tons per year or 550 lb/day. Subsequent SIP revisions have resulted in lower exemption levels where additional emission reductions have been required to demonstrate attainment. The TACB staff will be proposing additional rulemaking to comply with EPA requirements for reasonably available control technology exemption levels.

The sections are adopted under the Texas Clean Air Act (TCAA), §382.017, which provides the TACB with the authority to make rules consistent with the policy and purposes of the TCAA.

**§115.535. Testing Requirements.** For the counties referenced in §115.539 of this title (relating to Counties and Compliance Schedules), compliance with this undesignated head concerning pharmaceutical manufacturing facilities, shall be determined by applying the following test methods, as appropriate:

(1) Test Methods 1-4 (40 Code of Federal Regulation 60, Appendix A) for determining flow rate, as necessary;

(2) Test Method 18 (40 Code of Federal Regulations 60, Appendix A) for determining gaseous organic compound emissions by gas chromatography;

(3) Test Method 25 (40 Code of Federal Regulations 60, Appendix A) for determining total gaseous nonmethane organic emissions as carbon;

(4) Test Methods 25A or 25B (40 Code of Federal Regulations 60, Appendix A) for determining total gaseous organic concentrations using flame ionization or nondispersive infrared analysis;

(5) determination of true vapor pressure using American Society of Testing and Materials Test Method D323-82 for the measurement of Reid vapor pressure, adjusted for actual storage temperature in accordance with API Publication 2517, Third Edition, 1989; or

(6) minor modifications to these test methods approved by the executive director.

**§115.539. Counties and Compliance Schedules.** All affected persons in Brazoria, Dallas, El Paso, Galveston, Gregg, Harris, Jefferson, Nueces, Orange, Tarrant, and Victoria Counties shall be in compliance with this undesignated head concerning pharmaceutical manufacturing facilities in accordance with the following schedules.

(1) All compliance schedules which have expired prior to February 1, 1990, in accordance with §115.930 of this title (relating to Compliance Dates).

(2) All persons in Brazoria, Dallas, El Paso, Galveston, Harris, Jefferson, Orange, or Tarrant Counties affected by the provisions of §115.536 of this title (relating to Recordkeeping Requirements) shall be in compliance with this section as soon as practicable but no later than December 31, 1990.

This agency hereby certifies that the rule as adopted has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

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Executive Director  
Texas Air Control Board

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