

# Rule History Title 30 Texas Administrative Code Chapter 115 Pharmaceutical Manufacturing Facilities

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## Introduction

The official version of the rules in [Chapter 115, Subchapter F, Division 2](#) is available on the Secretary of State's website.

Each revision is identified by the date the commission adopted the changes. When available, the rule project number, which is the unique identification number from the rules tracking database for the specific rule project, is also provided for reference.

The *Texas Register* publications of the rule proposal and adoption are given for each revision. The proposed rules are approved by the commissioners to be published in the *Texas Register* for public comment. Once adopted by the commissioners, the rules are republished as final in the *Texas Register*.

These rules are submitted for United States Environmental Protection Agency (EPA) approval as part of the State Implementation Plan (SIP) control strategy to meet the National Ambient Air Quality Standard (NAAQS) for ozone. Links to the *Federal Register* publication of the EPA's approval of these rules and the associated SIP revisions are also included.

The summary information includes the affected sections of the rule, the counties affected, the compliance date, and a brief description of the rule revisions. If the adopted rule does not provide for additional time to comply with any new or revised requirements then compliance with any rule revisions is required by the effective date of the rulemaking.

## Rule Project Adopted on 11/15/2006

### Rule project number 2006-011-115-EN

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Proposal: [31 TexReg 5558](#) (07/14/2006)

Adoption: [31 TexReg 9840](#) (12/08/2006)

Date submitted to EPA: 12/13/2006

EPA approval: [73 FR 40972](#) (07/17/2008)

Section affected:

- Amended: 115.539

Area affected:

- Dallas-Fort Worth (DFW) area (Ellis, Johnson, Kaufman, Parker and Rockwall Counties)

Compliance date: 03/01/2009 (Effective date: 12/07/2006)

Summary:

The rulemaking requires owners and operators of pharmaceutical manufacturing sources in the newly designated nonattainment counties (Ellis, Johnson, Kaufman, Parker, and Rockwall Counties) to comply with the same rules that currently apply to sources located in the other DFW counties (Collin, Dallas, Denton, and Tarrant Counties).

The rulemaking is necessary to satisfy federal reasonably available control technology (RACT) requirements for the new nonattainment counties as a result of the DFW nonattainment area's expansion under the 1997 eight-hour ozone NAAQS.

This rulemaking is part of the [DFW 1997 Eight-Hour Ozone Attainment Demonstration SIP Revision \(2006-013-SIP-NR\)](#) (05/23/2007).

## Rule Project Adopted on 04/26/2002

### Rule project number 2002-037-115-AI

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Proposal: [27 TexReg 49](#) (01/04/2002)

Adoption: [27 TexReg 4113](#) (05/10/2002)

Date submitted to EPA: 07/18/2002

EPA approval: [73 FR 10383](#) (02/27/2008)

Sections affected:

- Amended: 115.532, 115.533, 115.535, and 115.539

Areas affected:

- Beaumont-Port Arthur (BPA) area (Hardin, Jefferson, and Orange Counties)
- Corpus Christi area (Nueces County)
- DFW area (Collin, Dallas, Denton, and Tarrant Counties)
- El Paso area (El Paso County)
- Houston-Galveston-Brazoria (HGB) area (Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, and Waller Counties)
- Northeast Texas area (Gregg County)
- Victoria area (Victoria County)

Compliance date: Not applicable (Effective date: 05/16/2002)

Summary:

The amendments update rule references and terminology and condense the alternate control requirements for all affected areas into one paragraph.

## Rule Project Adopted on 04/30/1997

### Rule project number 1996-164-115-AI

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Proposal: [21 TexReg 11231](#) (11/19/1996)

Adoption: [22 TexReg 4213](#) (05/13/1997)

Date submitted to EPA: 05/21/1997

EPA approval: [64 FR 3841](#) (01/26/1999)

Sections affected:

- Amended: 115.532, 115.533, 115.536, 115.537, and 115.539

Areas affected:

- BPA area (Hardin, Jefferson, and Orange Counties)
- Corpus Christi area (Nueces County)
- DFW area (Collin, Dallas, Denton, and Tarrant Counties)
- El Paso area (El Paso)
- HGB area (Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, and Waller Counties)
- Northeast Texas area (Gregg County)
- Victoria area (Victoria County)

Compliance date: Not applicable (Effective date: 05/22/1997)

Summary:

The rulemaking deletes language made obsolete by the passing of the compliance date and updates rule references and terminology.

## Rule Project Adopted on 05/04/1994

### No Rule Project Number

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Proposal: [18 TexReg 9916](#) (12/24/1993)

Adoption: [19 TexReg 3703](#) (05/13/1994)

Date submitted to EPA: 05/09/1994

EPA approval:

- [62 FR 27964](#) (05/22/1997)

Sections affected:

- Amended: 115.532

Areas affected:

- BPA area (Hardin, Jefferson, and Orange Counties)
- DFW area (Collin, Dallas, Denton, and Tarrant Counties)
- El Paso area (El Paso)
- HGB area (Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, and Waller Counties)

Compliance date: Not applicable (Effective date: 05/27/1994)

Summary:

The rulemaking applies the "once-in, always-in" concept. The "once-in, always-in" concept ensures that once emissions from a source exceed the applicability cutoff for a particular volatile organic compounds (VOC) rule in the SIP, that source is always subject to the control requirements of the regulation.

## Rule Project Adopted on 10/16/1992

### No Rule Project Number

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Proposal: [17 TexReg 4671](#) (06/30/1992)

Adoption: [17 TexReg 7782](#) (11/03/1992)

Date submitted to EPA: 11/13/1992

EPA approval: [60 FR 12438](#) (03/07/1995)

Sections affected:

- Amended: 115.536 and 115.539

Area affected:

- Victoria area (Victoria County)

Compliance date: 07/31/1993 (Effective date: 11/16/1992)

Summary:

The rulemaking updates monitoring and recordkeeping to specify that the operational parameters of any emission control device monitor must be continuously monitored and recorded for sources in Victoria County. This rulemaking is necessary to facilitate reclassification to an ozone attainment county.

This rulemaking is part of the [Victoria Redesignation Request and Maintenance SIP Revision](#) (07/27/1994).

## Rule Project Adopted on 05/08/1992

### No Rule Project Number

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Proposal: [17 TexReg 667](#) (01/28/1992)

Adoption: [17 TexReg 4683](#) (06/30/1992)

Date submitted to EPA: 06/08/1992

EPA approval: [60 FR 12438](#) (03/07/1995)

Sections affected:

- Amended: 115.531-115.537 and 115.539

Areas affected:

- BPA area (Hardin, Jefferson, and Orange Counties)
- DFW area (Collin and Denton Counties)
- HGB area (Brazoria, Chambers, Fort Bend, Liberty, Montgomery, and Waller Counties)

Compliance date: 07/31/1993 (Effective date: 08/01/1992)

Summary:

The rulemaking extends controls to pharmaceutical manufacturing processes located in the counties that have recently been designated as nonattainment (Chambers, Collin, Denton, Fort Bend, Hardin, Liberty, Montgomery, and Waller Counties).

The rulemaking lowers the exemption threshold for processes in the affected counties other than Dallas, El Paso, Harris, and Tarrant Counties to 15 pounds of VOC emissions per 24-hour period.

The rulemaking also moves the existing requirements for sources in Gregg, Nueces, and Victoria Counties to a separate subsection in each section, but does not impose any new requirements on sources in these three counties.

The rulemaking is necessary to ensure all nonattainment counties are subject to the same level of control to satisfy federal RACT requirements and is part of the [15% ROP SIP Revision \(Phase I\)](#) (11/10/1993).

## Rule Project Adopted on 05/10/1991

### No Rule Project Number

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Proposal: [16 TexReg 854](#) (02/12/1991)

Adoption: [16 TexReg 3729](#) (07/02/1991)

Date submitted to EPA: 05/10/1991

EPA approval: [57 FR 44124](#) (09/24/1992)

Sections affected:

- Amended: 115.532, 115.536, 115.537, and 115.539

Areas affected:

- DFW area (Dallas and Tarrant Counties)
- El Paso area (El Paso County)

Compliance date: 07/31/1992 (Effective date: 07/17/1991)

Summary:

The rulemaking lowers the exemption threshold to at least 15 pound of VOC emissions per 24-hour period from 550 pound of VOC emissions per 24-hour period. The rulemaking also adds a monitoring and recordkeeping requirement to monitor carbon adsorption systems to determine if a breakthrough has occurred and specifies that if exemption limits are exceeded, then the control requirements become applicable by May 31, 1991.

This rulemaking is part of the [15% ROP SIP Revision \(Phase I\)](#) (11/10/1993).



## Rule Project Adopted on 12/08/1989

### No Rule Project Number

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Proposal: [14 TexReg 3674](#) (07/28/1989)

Adoption: [15 TexReg 586](#) (02/02/1990)

Date submitted to EPA: 03/05/1990

EPA approval: [57 FR 44124](#) (09/24/1992)

Sections affected:

- New: 115.531-115.537 and 115.539

Areas affected:

- BPA area (Jefferson and Orange Counties)
- Corpus Christi area (Nueces County)
- DFW area (Dallas and Tarrant Counties)
- El Paso area (El Paso County)
- HGB area (Brazoria, Galveston, and Harris)
- Northeast Texas area (Gregg County)
- Victoria area (Victoria County)

Compliance date: 12/31/1990 (Effective date: 02/19/1990)

Summary:

The rulemaking establishes pharmaceutical manufacturing requirements. The rulemaking is part of the reorganization and reformatting of the Chapter 115 rules, but no substantive changes are made to the rule requirements. This rulemaking is concurrent with the repeal of Sections 115.231-115.233 (12/08/1989).

## Rule Project Adopted on 12/08/1989

### No Rule Project Number

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Proposal: [14 TexReg 3674](#) (07/28/1989)

Adoption: [15 TexReg 586](#) (02/02/1990)

Date submitted to EPA: 03/05/1990

EPA approval: [57 FR 44124](#) (09/24/1992)

Sections affected:

- Repealed: 115.231-115.233

Areas affected:

- BPA area (Jefferson and Orange Counties)
- Corpus Christi area (Nueces County)
- DFW area (Dallas and Tarrant Counties)
- El Paso area (El Paso County)
- HGB area (Brazoria, Galveston, and Harris)
- Northeast Texas area (Gregg County)
- Victoria area (Victoria County)

Compliance date: 12/31/1990 (Effective date: 02/19/1990)

Summary:

The rulemaking repeals the entire Chapter 115 rules, including the surface coating process rules. This rulemaking is concurrent with the adoption the new Chapter 115 (12/08/1989).

## Rule Project Adopted on 01/08/1982

### No Rule Project Number

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Proposal: [6 TexReg 2871](#) (08/07/1981)

Adoption: [7 TexReg 911](#) (03/05/1982)

Date submitted to EPA: 08/09/1982 and 01/13/1983

EPA approval: [48 FR 8072](#) (02/25/1983)

Sections affected:

- Amended: 115.231-115.233

Areas affected:

- San Antonio area (Bexar County)

Compliance date: 12/31/1982 (Effective date: 03/31/1982)

Summary:

The rulemaking removes Bexar County from the rule applicability since Bexar County has been reclassified to attainment ([46 FR 56199](#) (11/16/1981)).

## Rule Project Adopted on 07/11/1980

### No Rule Project Number

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Proposal: [5 TexReg 1316](#) (04/04/1980)

Adoption: [5 TexReg 3256](#) (08/12/1980)

Date submitted to EPA: 07/25/1980

EPA approval: [47 FR 18857](#) (05/03/1982)

Sections affected:

- New: 115.231-115.233

Areas affected:

- BPA area (Jefferson and Orange Counties)
- Corpus Christi area (Nueces County)
- DFW area (Dallas and Tarrant Counties)
- El Paso area (El Paso County)
- HGB area (Brazoria, Galveston, and Harris)
- Northeast Texas area (Gregg County)
- San Antonio area (Bexar County)
- Victoria area (Victoria County)

Compliance date: 12/31/1982 (Effective date: 08/22/1980)

Summary:

The rulemaking establishes requirements for pharmaceutical manufacturing processes in Harris County with VOC emissions of at least 15 pounds per 24-hour period and in the other affected areas with VOC emissions of at least 550 pounds per 24-hour period.

The rules are based on the EPA's 1978 *Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products* control techniques guidelines document ([EPA-450/2-78-029](#)).

The rulemaking is necessary to satisfy federal reasonably available control technology requirements and is part of the [Harris Ozone SIP Revision](#) (12/03/1982).