

believe the petitioners have exhausted their lines of argument in their rehearing requests and nothing would be gained by delaying the effect of our action in order to proceed with a different administrative vehicle to arrive at the same result.

The Commission Orders

The requests for rehearing and reconsideration are denied as discussed in the body of this order.

By the Commission.

Lois D. Cashell,
Secretary.

[FR Doc. 95-321 Filed 1-5-95; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority in order to redelegate authorities relating to determining the classification of devices first marketed after May 28, 1976, to additional officials in the Center for Devices and Radiological Health (CDRH).

EFFECTIVE DATE: January 6, 1995.

FOR FURTHER INFORMATION CONTACT:

Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4765, or

Ellen R. Rawlings, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: FDA is amending § 5.51 *Determination of classification of devices* (21 CFR 5.51) by extending the authority in § 5.51(b)(1) to determine the classification of a medical device first intended for commercial distribution after May 28, 1976, pursuant to section 513(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act, to Deputy Division Directors, Associate Division Directors, and Branch Chiefs, Office of Device Evaluation, CDRH. The expanded

delegation will ensure greater efficiency in making these classification decisions.

Further redelegation of the authority delegated is not authorized at this time. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50, 61-63, 141-149, 467f, 679(b), 801-886, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354, 361, 362, 1701-1706, 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b, 264, 265, 300u-300u-5, 300aa-1, 300aa-25, 300aa-27, 300aa-28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660 (42 U.S.C. 300aa-1 note).

2. Section 5.51 is amended by revising paragraph (b)(1) to read as follows:

§ 5.51 Determination of classification of devices.

* * * * *

(b) * * *

(1) The Director and Deputy Director, CDRH, and the Director, Deputy Director, Associate Director, Chief of the Premarket Notification Section, Division and Deputy Division Directors, Associate Division Directors, and Branch Chiefs, Office of Device Evaluation, CDRH.

* * * * *

Dated: December 29, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 95-359 Filed 1-5-95; 8:45 am]

BILLING CODE 4160-01-P-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[LA-13-1-6389; FRL-5125-8]

Approval and Promulgation of Implementation Plan: Louisiana Emission Statement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action approves a revision to the Louisiana State Implementation Plan (SIP) to include revisions to the Louisiana Department of Environmental Quality (LDEQ) Regulation Title 33, Part III, Chapter 9, *General Regulations on Control of Emissions and Emission Standards*, Section 919, *Emission Inventory*. These revisions are for the purpose of implementing an emission statement program for stationary sources within the ozone nonattainment areas. The implementation plan was submitted by the State to satisfy the Federal requirements for an emission statement program as part of the SIP for Louisiana. **EFFECTIVE DATE:** This final rule is effective on February 6, 1995.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the following locations. Interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

U.S. Environmental Protection Agency, Region 6, Air Programs Branch (6T-AP), 1445 Ross Avenue, suite 700, Dallas, Texas 75202-2733

U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center, 401 M Street, SW., Washington, DC 20460
Louisiana Department of Environmental Quality, Air Quality Division, 7290 Bluebonnet, Baton Rouge, Louisiana 70810.

FOR FURTHER INFORMATION CONTACT: Mr. Herbert R. Sherrow, Jr., Planning Section (6T-AP), Air Programs Branch, USEPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, Telephone (214) 655-7237.

SUPPLEMENTARY INFORMATION:

Background

The air quality planning and SIP requirements for ozone nonattainment and transport areas are set out in subparts I and II of part D of title I of the Clean Air Act (CAA or "the Act"),

as amended by the Clean Air Act Amendments (CAAA) of 1990. The EPA has published a "General Preamble" describing the EPA's preliminary views on how the EPA intends to review SIPs and SIP revisions submitted under title I of the CAA, including those State submittals for ozone transport areas within the States (see 57 FR 13498 (April 16, 1992) ("SIP: General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990"), 57 FR 18070 (April 28, 1992) ("Appendices to the General Preamble"), and 57 FR 55620 (November 25, 1992) ("SIP: NO_x Supplement to the General Preamble")).

The EPA has also issued a draft guidance document describing the requirements for the emission statement programs discussed in this document, entitled "Guidance on the Implementation of an Emission Statement Program" (July 1992).

Section 182 of the Act sets out a graduated control program for ozone nonattainment areas. Section 182(a) sets out requirements applicable in marginal nonattainment areas, which are also made applicable in subsections (b), (c), (d), and (e) to all other ozone nonattainment areas. Among the requirements in section 182(a) is a program in paragraph (3) of that subsection for stationary sources to prepare and submit to the State each year emission statements showing actual emissions of volatile organic compounds (VOC) and nitrogen oxides (NO_x). This paragraph provides that the States are to submit a revision to their SIPs by November 15, 1992, establishing this emission statement program.

The State passed an emergency regulation after following all applicable State Administrative Procedures Act requirements for submittal to the EPA by November 15, 1992, to satisfy CAA requirements. The State subsequently entered into State rulemaking for a permanent regulation. It was submitted to public hearing on December 20, 1992. The State addressed public comments and made minor adjustments. Following the public hearing, the final rule was adopted by the State and submitted to the EPA as a proposed revision to the SIP on March 3, 1993. The permanent emission statement regulations were then codified at LAC 33:III.919.

Technical Correction

In reviewing the State's submitted permanent regulation, technical errors were discovered in subsections B.2.a. and B.2.d. Subsection B.2.a. contains a reference to subsection B.2.d., when it should refer to subsection B.2.c. Subsection B.2.d. omitted a reference to

subsection B.2.c. The State prepared a technical correction to the rule and submitted the revised rule to public hearing. Following the public hearing, the rule was adopted by the State on October 20, 1994. On November 15, 1994, the State submitted documentation to the EPA substantiating that the technical correction had been adopted.

Response to Comments

The EPA proposed approval of the Louisiana emission statement regulations on April 7, 1994 (59 FR 16582-16585), and no comments were received regarding the proposed approval.

Final Action

In today's action, the EPA is approving the Louisiana emission statement program SIP submittal.

The analysis of the Louisiana regulation shows that it adequately addresses all components of an emission statement program.

In addition, the State has agreed to provide the EPA with emission statement data for the EPA Aerometric Information Retrieval System through the State's grants commitments and to provide status reports.

The EPA has reviewed this request for revision of the Federally-approved SIP for conformance with the provisions of the CAAA of November 15, 1990. The EPA has determined that this action conforms with those requirements.

This final action on the Louisiana emission statement SIP is unchanged from the April 7, 1994, proposed approval action with the exception of the State's confirmation of adoption of the corrected rule. The discussion herein provides only a broad overview of the proposed action that the EPA is now finalizing. The public is referred to the April 7, 1994, proposed approval **Federal Register** action for a full discussion of the action that the EPA is now finalizing.

This action makes final the action proposed at 59 FR 16582 (April 7, 1994). As noted elsewhere in this action, the EPA received no public comments on the proposed action. As a direct result, the Regional Administrator has reclassified this action from Table Two to Table Three under the processing procedures established at 54 FR 2214, January 19, 1989, and revised via memorandum from the Assistant Administrator for Air and Radiation to the Regional Administrators dated October 4, 1993.

Nothing in this action should be construed as permitting, allowing, or establishing a precedent for any future

request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economical, and environmental factors, and in relation to relevant statutory and regulatory requirements.

Regulatory Process

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, the EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities (5 U.S.C. 603 and 604). Alternatively, the EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

The SIP approvals under section 110 and subchapter I, part D, of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The CAA forbids the EPA to base its actions concerning SIPs on such grounds (*Union Electric Co. v. U.S. E.P.A.*, 427 U.S. 246, 256-66 (S. Ct. 1976; 42 U.S.C. 7410(a)(2)).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 7, 1995. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

Executive Order 12866

This action has been classified as a Table Three action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214-2225), as revised by an October 4, 1993, memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation. The Office of

Management and Budget (OMB) has exempted this action from review under Executive Order 12866.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Emission statements, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen oxide, Oxides of nitrogen, SIP requirements, Volatile organic compounds.

Note: Incorporation by reference of the SIP for the State of Louisiana was approved by the Director of the Federal Register on July 1, 1982.

Dated: December 6, 1994.

William B. Hathaway,
Acting Regional Administrator.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart T—Louisiana

2. Section 52.970 is amended by adding paragraph (c)(65) to read as follows:

§ 52.970 Identification of plan.

* * * * *

(c) * * *

(65) Revisions to the Louisiana Department of Environmental Quality Regulation Title 33, Part III, Chapter 9, Section 919, (February 2, 1993), and a technical correction (October 20, 1994). These revisions are for the purpose of implementing an emission statement program for stationary sources within the ozone nonattainment areas.

(i) Incorporation by reference.

(A) Revisions to LAC, title 33, Part III, Chapter 9, *General Regulations on Control of Emissions and Emissions Standards*, Section 919, *Emission Inventory*, adopted in the *Louisiana Register*, Vol. 19, No. 2, 184–186, February 20, 1993. All subsections except B.2.a. and B.2.d.

(B) Revisions to LAC, title 33, Part III, Chapter 9, *General Regulations on Control of Emissions and Emissions standards*, Section 919, *Emission Inventory*, adopted in the *Louisiana Register*, Vol 20, No. 10, 1102, October 20, 1994. Subsections B.2.a. and B.2.d.

[FR Doc. 95–290 Filed 1–5–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[MA–26–1–6173a; A–1–FRL–5123–5]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; RACT for Nichols and Stone Company

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the Commonwealth of Massachusetts. This revision establishes and requires reasonably available control technology (RACT) for Nichols & Stone Company in Gardner, MA. The intended effect of this action is to approve a source specific RACT determination made by Massachusetts in accordance with the commitments specified in its Ozone Attainment Plan approved by EPA on November 9, 1983. This action is being taken in accordance with section 110 of the Clean Air Act.

DATES: This final rule is effective March 7, 1995, unless notice is received by February 6, 1995 that adverse or critical comments will be submitted. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments may be mailed to Linda M. Murphy, Director, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region I, JFK Federal Building, Boston, MA 02203. Copies of the documents relevant to this action are available for public inspection during normal business hours, by appointment at the Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region I, One Congress Street, 10th floor, Boston, MA; and Division of Air Quality Control, Department of Environmental Protection, One Winter Street, 8th Floor, Boston, MA 02108.

FOR FURTHER INFORMATION CONTACT: Jeanne Cosgrove, (617) 565–3246.

SUPPLEMENTARY INFORMATION: On July 19, 1993 and October 27, 1993, the Massachusetts Department of Environmental Protection (DEP) submitted a formal revision to its State Implementation Plan (SIP). The SIP revision consists of a final plan approval issued to Nichols & Stone Company, effective June 30, 1993. The plan approval establishes and requires reasonably available control technology (RACT) to control volatile organic compound (VOC) emissions from Nichols & Stone in Gardner, Massachusetts.

Summary of SIP Revision

The DEP issued this plan approval pursuant to the requirements found in 310 CMR 7.18(17), which was approved by EPA on November 9, 1983 (48 FR 51480) as part of Massachusetts' Ozone Attainment Plan. Massachusetts Regulation 310 CMR 7.18(17), "Reasonably Available Control Technology (RACT)," requires the DEP to determine and impose RACT on otherwise unregulated stationary sources of VOC with the potential to emit greater than or equal to 100 tons per year.

For the reasons outlined in the Technical Support Document prepared for this revision, EPA believes that the limits the DEP has established represent RACT for Nichols & Stone.

The plan approval, dated June 30, 1993, requires Nichols & Stone to meet a 12 month rolling average VOC limit of 98 tons for the entire facility. To ensure short term compliance and enforceability, the MA DEP has set the following emission limitations on the VOC content in the coatings as applied to the wood furniture:

Description of coating	Lbs. VOC/gallon of coating (less water) as applied
Stains	6.63
Sealers	4.91
Black Undercoat	6.29
Lacquer Sheen topcoat (to be used specifically for the college chair business)	5.6
Topcoats (except for lacquer sheens)	4.7
Toner	6.67
colored lacquer	6.11

Other RACT conditions include high volume low pressure (HVLP) technology, good housekeeping practices and recordkeeping/monitoring requirements. Nichols & Stone is required to minimize air emissions by using HVLP technology for all finishing operations, except for staining of chairs which use flow coaters, decorative hand painting and small touch up/repair work. Small touch up/repair work using air-assisted spray guns must not exceed 5 gallons of coating per day for the entire facility. All VOC formulations must be stored in covered containers. Spray guns must be enclosed during cleaning or cleaned without solvents. To evaluate compliance, the plan approval requires Nichols & Stone to maintain daily records of the identity, quantity and VOC content of each coating as applied.

EPA is publishing this action without prior proposal because the Agency