

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 63****National Emission Standards for Hazardous Air Pollutants for Pharmaceuticals Production***CFR Correction*

In Title 40 of the Code of Federal Regulations, Part 63 (§ 63.1200 to End), revised as of July 1, 2001, in § 63.1257, on page 134, redesignate paragraph (d)(4)(iii) as paragraph (d)(3)(iii), and on page 140, remove the second definition of  $\rho$  following equation 47.

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**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 63**

[WV001-1000a; FRL-7166-6]

**Approval of Section 112(l) Authority for Hazardous Air Pollutants; State of West Virginia; Department of Environmental Protection**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule and delegation.

**SUMMARY:** EPA is taking direct final action to approve West Virginia Department of Environmental Protection's (WVDEP's) request for delegation of authority to implement and enforce its hazardous air pollutant regulations for perchloroethylene drycleaning facilities, hard and decorative chromium electroplating and chromium anodizing tanks, ethylene oxide sterilization facilities, halogenated solvent cleaning, and secondary lead smelting which have been adopted by reference from the Federal requirements set forth in the Code of Federal Regulations. This approval will automatically delegate future amendments to these regulations once WVDEP incorporates these amendments into its regulations. In addition, EPA is taking direct final action to approve of WVDEP's mechanism for receiving delegation of future hazardous air pollutant regulations. This mechanism entails WVDEP's incorporation by reference of the unchanged Federal standard into its hazardous air pollutant regulation and WVDEP's notification to EPA of such incorporation. EPA is not waiving its notification and reporting requirements under this approval; therefore, sources will need to send notifications and reports to both

WVDEP and EPA. This action pertains only to affected sources, as defined by the Clean Air Act's (CAA's or the Act's) hazardous air pollutant program, which are not located at major sources, as defined by the Act's operating permit program. The WVDEP's request for delegation of authority to implement and enforce its hazardous air pollutant regulations at affected sources which are located at major sources, as defined by the Act's operating permit program, was initially approved on March 19, 2001. EPA is taking this action in accordance with the CAA.

**DATES:** This direct final rule will be effective June 3, 2002, unless EPA receives adverse or critical comments by May 2, 2002. If adverse comment is received, EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

**ADDRESSES:** Written comments on this action should be sent concurrently to: Makeba A. Morris, Chief, Permits and Technical Assessment Branch, Mail Code 3AP11, Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, PA 19103-2029, and John A. Benedict, West Virginia Department of Environmental Protection, Division of Air Quality, 7012 MacCorkle Avenue, SE, Charleston, WV 25304-2943. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103 and the West Virginia Department of Environmental Protection, Division of Air Quality, 7012 MacCorkle Avenue, SE, Charleston, WV 25304-2943.

**FOR FURTHER INFORMATION CONTACT:** Dianne J. McNally, U.S. Environmental Protection Agency, Region 3, 1650 Arch Street (3AP11), Philadelphia, PA 19103-2029, [mcnally.dianne@epa.gov](mailto:mcnally.dianne@epa.gov) (telephone 215-814-3297). Please note that any formal comments must be submitted, in writing, as provided in the **ADDRESSES** section of this document.

**SUPPLEMENTARY INFORMATION:****I. Background**

Section 112(l) of the Act and 40 Code of Federal Regulations (CFR) part 63, subpart E authorize EPA to approve of State rules and programs to be implemented and enforced in place of certain CAA requirements, including the National Emission Standards for Hazardous Air Pollutants set forth at 40 CFR part 63. EPA promulgated the program approval regulations on

November 26, 1993 (58 FR 62262) and subsequently amended these regulations on September 14, 2000 (65 FR 55810). An approvable State program must contain, among other criteria, the following elements:

(a) A demonstration of the state's authority and resources to implement and enforce regulations that are at least as stringent as the NESHAP requirements;

(b) a schedule demonstrating expeditious implementation of the regulation; and

(c) a plan that assures expeditious compliance by all sources subject to the regulation.

On November 18, 1999, WVDEP submitted to EPA a request to receive delegation of authority to implement and enforce the hazardous air pollutant regulations for the affected sources defined in 40 CFR part 63. On March 19, 2001, WVDEP received delegation of authority to implement all emission standards promulgated in 40 CFR part 63, as they apply to major sources, as defined by 40 CFR part 70. On June 15, 2001, WVDEP supplemented their November 18, 1999 request with information necessary to address delegation of the hazardous air pollutant regulations for affected sources which are not located at major sources, as defined by 40 CFR part 70. At the present time, the delegation request pertaining to affected sources which are not located at major sources, as defined by 40 CFR part 70, includes the regulations for perchloroethylene drycleaning facilities, hard and decorative chromium electroplating and chromium anodizing tanks, ethylene oxide sterilization facilities, halogenated solvent cleaning, and secondary lead smelting which have been adopted by reference from the Federal requirements set forth in 40 CFR part 63, subparts M, N, O, T, and X, respectively. The WVDEP also requested that EPA automatically delegate future amendments to these regulations and approve WVDEP's mechanism for receiving delegation of future hazardous air pollutant regulations which it adopts unchanged from the Federal requirements. This mechanism entails WVDEP's incorporation by reference of the unchanged Federal standard into its regulation for hazardous air pollutant sources at 45CSR34 and WVDEP's notification to EPA of such incorporation.

**II. EPA's Analysis of WVDEP's Submittal**

Based on WVDEP's program approval request and its pertinent laws and regulations, EPA has determined that

such an approval is appropriate in that WVDEP has satisfied the criteria of 40 CFR 63.91. In accordance with 40 CFR 63.91(d)(3)(i), WVDEP submitted a written finding by the State Attorney General which demonstrates that the State has the necessary legal authority to implement and enforce its regulations, including the enforcement authorities which meet 40 CFR 70.11, the authority to request information from regulated sources and the authority to inspect sources and records to determine compliance status. In accordance with 40 CFR 63.91(d)(3)(ii), West Virginia submitted copies of its statutes, regulations and requirements that grant authority to WVDEP to implement and enforce the regulations. In accordance with 40 CFR 63.91(d)(3)(iii)-(v), WVDEP submitted documentation of adequate resources and a schedule and plan to assure expeditious State implementation and compliance by all sources. Therefore, the WVDEP program has adequate and effective authorities, resources, and procedures in place for implementation and enforcement of sources subject to the requirements of 40 CFR part 63, subparts M, N, O, T, and X, as well as any future emission standards, should WVDEP seek delegation for these standards. The WVDEP adopts the emission standards promulgated in 40 CFR part 63 into the State regulation for hazardous air pollutant sources found at 45CSR34. The WVDEP has the primary authority and responsibility to carry out all elements of these programs for all sources covered in West Virginia, including on-site inspections, record keeping reviews, and enforcement.

### III. Terms of Program Approval and Delegation of Authority

In order for WVDEP to receive automatic delegation of future amendments to the perchloroethylene drycleaning facilities, hard and decorative chromium electroplating and chromium anodizing tanks, ethylene oxide sterilization facilities, halogenated solvent cleaning, and secondary lead smelting regulations, as they apply to facilities that are not located at major sources, as defined by 40 CFR part 70, each amendment must be legally adopted by the State of West Virginia. As stated earlier, these amendments are adopted into West Virginia's regulation for hazardous air pollutant sources at 45CSR34. The delegation of amendments to these rules will be finalized on the effective date of the legal adoption. The WVDEP will notify EPA of its adoption of the Federal regulation amendments.

EPA has also determined that WVDEP's mechanism for receiving delegation of future hazardous air pollutant regulations which it adopts unchanged from the Federal requirements, as they apply to facilities that are not located at major sources, as defined by 40 CFR part 70, is approvable. This mechanism requires WVDEP to adopt the Federal regulation into its regulation for hazardous air pollutant sources at 45CSR34. The delegation will be finalized on the effective date of the legal adoption. The WVDEP is also required to notify EPA of its adoption of the Federal regulation. The official notice of delegation of additional emission standards will be published in the **Federal Register**. As noted earlier, WVDEP's program to implement and enforce all emission standards promulgated under 40 CFR part 63, as they apply to major sources, as defined by 40 CFR part 70, was previously approved on March 19, 2001.

The notification and reporting provisions in 40 CFR part 63 requiring the owners or operators of affected sources to make submissions to the Administrator shall be met by sending such submissions to WVDEP and EPA Region III.

If at any time there is a conflict between a WVDEP regulation and a Federal regulation, the Federal regulation must be applied if it is more stringent than that of WVDEP. EPA is responsible for determining stringency between conflicting regulations. If WVDEP does not have the authority to enforce the more stringent Federal regulation, it shall notify EPA Region III in writing as soon as possible, so that this portion of the delegation may be revoked.

If EPA determines that WVDEP's procedure for enforcing or implementing the 40 CFR part 63 requirements is inadequate, or is not being effectively carried out, this delegation may be revoked in whole or in part in accordance with the procedures set out in 40 CFR 63.96(b).

Certain provisions of 40 CFR part 63 allow only the Administrator of EPA to take further standard setting actions. In addition to the specific authorities retained by the Administrator in 40 CFR 63.90(d) and the "Delegation of Authorities" section for specific standards, EPA Region III is retaining the following authorities, in accordance with 40 CFR 63.91(g)(2)(ii):

- (1) Approval of alternative non-opacity emission standards, *e.g.*, 40 CFR 63.6(g) and applicable sections of relevant standards;
- (2) Approval of alternative opacity standards, *e.g.*, 40 CFR 63.9(h)(9) and

applicable sections of relevant standards;

(3) Approval of major alternatives to test methods, as defined in 40 CFR 63.90(a), *e.g.*, 40 CFR 63.7(e)(2)(ii) and (f) and applicable sections of relevant standards;

(4) Approval of major alternatives to monitoring, as defined in 40 CFR 63.90(a), *e.g.*, 40 CFR 63.8(f) and applicable sections of relevant standards; and

(5) Approval of major alternatives to recordkeeping and reporting, as defined in 40 CFR 63.90(a), *e.g.*, 40 CFR 63.10(f) and applicable sections of relevant standards.

The following provisions are included in this delegation, in accordance with 40 CFR 63.91(g)(1)(i), and can only be exercised on a case-by-case basis. When any of these authorities are exercised, WVDEP must notify EPA Region III in writing:

(1) Applicability determinations for sources during the title V permitting process and as sought by an owner/operator of an affected source through a formal, written request, *e.g.*, 40 CFR 63.1 and applicable sections of relevant standards<sup>1</sup>;

(2) Responsibility for determining compliance with operation and maintenance requirements, *e.g.*, 40 CFR 63.6(e) and applicable sections of relevant standards;

(3) Responsibility for determining compliance with non-opacity standards, *e.g.*, 40 CFR 63.6(f) and applicable sections of relevant standards;

(4) Responsibility for determining compliance with opacity and visible emission standards, *e.g.*, 40 CFR 63.6(h) and applicable sections of relevant standards;

(5) Approval of site-specific test plans<sup>2</sup>, *e.g.*, 40 CFR 63.7(c)(2)(i) and (d)

<sup>1</sup> Applicability determinations are considered to be nationally significant when they: (i) Are unusually complex or controversial; (ii) Have bearing on more than one state or are multi-Regional; (iii) appear to create a conflict with previous policy or determinations; (iv) are a legal issue which has not been previously considered; or (v) raise new policy questions and shall be forwarded to EPA Region III prior to finalization. Detailed information on the applicability determination process may be found in EPA document 305-B-99-004 *How to Review and Issue Clean Air Act Applicability Determinations and Alternative Monitoring*, dated February 1999. The WVDEP may also refer to the Compendium of Applicability Determinations issued by the EPA and may contact EPA Region III for guidance.

<sup>2</sup> The WVDEP will notify EPA of these approvals on a quarterly basis by submitting a copy of the test plan approval letter. Any plans which propose major alternative test methods or major alternative monitoring methods shall be referred to EPA for approval.

and applicable sections of relevant standards;

(6) Approval of minor alternatives to test methods, as defined in 40 CFR 63.90(a), *e.g.*, 40 CFR 63.7(e)(2)(i) and applicable sections of relevant standards;

(7) Approval of intermediate alternatives to test methods, as defined in 40 CFR 63.90(a), *e.g.*, 40 CFR 63.7(e)(2)(ii) and (f) and applicable sections of relevant standards;

(8) Approval of shorter sampling times/volumes when necessitated by process variables and other factors, *e.g.*, 40 CFR 63.7(e)(2)(iii) and applicable sections of relevant standards;

(9) Waiver of performance testing, *e.g.*, 40 CFR 63.7 (e)(2)(iv), (h)(2), and (h)(3) and applicable sections of relevant standards;

(10) Approval of site-specific performance evaluation (monitoring) plans<sup>3</sup>, *e.g.*, 40 CFR 63.8(c)(1) and (e)(1) and applicable sections of relevant standards;

(11) Approval of minor alternatives to monitoring methods, as defined in 40 CFR 63.90(a), *e.g.*, 40 CFR 63.8(f) and applicable sections of relevant standards;

(12) Approval of intermediate alternatives to monitoring methods, as defined in 40 CFR 63.90(a), *e.g.*, 40 CFR 63.8(f) and applicable sections of relevant standards;

(13) Approval of adjustments to time periods for submitting reports, *e.g.*, 40 CFR 63.9 and 63.10 and applicable sections of relevant standards; and

(14) Approval of minor alternatives to recordkeeping and reporting, as defined in 40 CFR 63.90(a), *e.g.*, 40 CFR 63.10(f) and applicable sections of relevant standards.

As required, WVDEP and EPA Region III will provide the necessary written, verbal and/or electronic notification to ensure that each agency is fully informed regarding the interpretation of applicable regulations in 40 CFR part 63. In instances where there is a conflict between a WVDEP interpretation and a Federal interpretation of applicable regulations in 40 CFR part 63, the Federal interpretation must be applied if it is more stringent than that of WVDEP. Written, verbal and/or electronic notification will also be used to ensure that each agency is informed of the compliance status of affected sources in West Virginia. The WVDEP will comply with all of the requirements of 40 CFR

63.91(g)(1)(ii). Quarterly reports will be submitted to EPA by WVDEP to identify sources determined to be applicable during that quarter.

Although WVDEP has primary authority and responsibility to implement and enforce the hazardous air pollutant general provisions and hazardous air pollutant emission standards for perchloroethylene drycleaning facilities, hard and decorative chromium electroplating and chromium anodizing tanks, ethylene oxide sterilization facilities, halogenated solvent cleaning, and secondary lead smelting, nothing shall preclude, limit, or interfere with the authority of EPA to exercise its enforcement, investigatory, and information gathering authorities concerning this part of the Act.

#### IV. Final Action

EPA is approving WVDEP's request for delegation of authority to implement and enforce its hazardous air pollutant regulations for perchloroethylene drycleaning facilities, hard and decorative chromium electroplating and chromium anodizing tanks, ethylene oxide sterilization facilities, halogenated solvent cleaning, and secondary lead smelting which have been adopted by reference from 40 CFR part 63, subparts M, N, O, T, and X, respectively. This approval will automatically delegate future amendments to these regulations. In addition, EPA is approving of WVDEP's mechanism for receiving delegation of future hazardous air pollutant regulations which it adopts unchanged from the Federal requirements. This mechanism entails legal adoption by the State of West Virginia of the amendments or rules into WVDEP's regulation for hazardous air pollutant sources at 45CSR34 and notification to EPA of such adoption. This action pertains only to affected sources, as defined by 40 CFR part 63, which are not located at major sources, as defined by 40 CFR part 70. The delegation of authority shall be administered in accordance with the terms outlined in section IV., above. This delegation of authority is codified in 40 CFR 63.99. In addition, WVDEP's delegation of authority to implement and enforce 40 CFR part 63 emission standards at major sources, as defined by 40 CFR part 70, approved by EPA Region III on March 19, 2001, is codified in 40 CFR 63.99.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial rule and anticipates no adverse comment because WVDEP's request for delegation of the hazardous air pollutant regulations pertaining to

perchloroethylene drycleaning facilities, hard and decorative chromium electroplating and chromium anodizing tanks, ethylene oxide sterilization facilities, halogenated solvent cleaning, and secondary lead smelting and its request for automatic delegation of future amendments to these rules and future standards, when specifically identified, does not alter the stringency of these regulations and is in accordance with all program approval regulations. However, in the "Proposed Rules" section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve of WVDEP's request for delegation if adverse comments are filed. This rule will be effective on June 3, 2002, without further notice unless EPA receives adverse comment by May 2, 2002. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

#### V. Administrative Requirements

##### A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the

<sup>3</sup> The WVDEP will notify EPA of these approvals on a quarterly basis by submitting a copy of the performance evaluation plan approval letter. Any plans which propose major alternative test methods or major alternative monitoring methods shall be referred to EPA for approval.

Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant. In reviewing requests for rule approval under CAA section 112, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove requests for rule approval under CAA section 112 for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a request for rule approval under CAA section 112, to use VCS in place of a request for rule approval under CAA section 112 that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### *B. Submission to Congress and the Comptroller General*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General

of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### *C. Petitions for Judicial Review*

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 June 3, 2002. 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, pertaining to the approval of WVDEP's delegation of authority for the hazardous air pollutant emission standards for perchloroethylene dry cleaning facilities, hard and decorative chromium electroplating and chromium anodizing tanks, ethylene oxide sterilizers, halogenated solvent cleaning, and secondary lead smelting (CAA section 112), may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

#### **List of Subjects 40 CFR Part 63**

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations.

Dated: March 21, 2002.

**Judith M. Katz,**

*Director, Air Protection Division, Region III.*

40 CFR part 63 is amended as follows:

#### **PART 63—[AMENDED]**

1. The authority citation for part 63 continues to read as follows:

**Authority:** 42 U.S.C. 7401, *et seq.*

#### **Subpart E—Approval of State Programs and Delegation of Federal Authorities**

2. Section 63.99 is amended by adding paragraph (a)(48) to read as follows:

#### **§ 63.99 Delegated Federal authorities**

(a) \* \* \*

(48) *West Virginia.* (i) West Virginia is delegated the authority to implement and enforce all existing and future unchanged 40 CFR part 63 standards at major sources, as defined in 40 CFR part 70, in accordance with the delegation

agreement between EPA Region III and the West Virginia Department of Environmental Protection, dated March 19, 2001, and any mutually acceptable amendments to that agreement.

(ii) West Virginia is delegated the authority to implement and enforce all existing 40 CFR part 63 standards and all future unchanged 40 CFR part 63 standards, if delegation is sought by the West Virginia Department of Environmental Protection and approved by EPA Region III, at affected sources which are not located at major sources, as defined in 40 CFR part 70, in accordance with the final rule, dated April 2, 2002, effective June 3, 2002, and any mutually acceptable amendments to the terms described in the direct final rule.

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#### **ENVIRONMENTAL PROTECTION AGENCY**

#### **40 CFR Part 745**

#### **Lead; Identification of Dangerous Levels of Lead**

#### *CFR Correction*

In Title 40 of the Code of Federal Regulations, Parts 700 to 789, revised as of July 1, 2001, on page 503, in § 745.227, add paragraph (i) to read as follows:

#### **§ 745.227 Work practice standards for conducting lead-based paint activities: target housing and child-occupied facilities.**

\* \* \* \* \*

(i) *Recordkeeping.* All reports or plans required in this section shall be maintained by the certified firm or individual who prepared the report for no fewer than 3 years. The certified firm or individual also shall provide copies of these reports to the building owner who contracted for its services.

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