

EPA-APPROVED KENTUCKY NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
Kentucky portion of the Ashland-Huntington Sulfur Dioxide Maintenance Plan.	Boyd County	05/13/05	05/24/06 [Insert first page number of publication].	

PART 81—[AMENDED]

■ 1. The authority citation for part 81 continues to read as follows:

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

■ 2. In § 81.318, the table entitled “Kentucky SO₂” is amended by revising the entry for “That portion of Boyd

County south of UTM northing line 4251 km” to read as follows:

§ 81.318 Kentucky.

* * * * *

KENTUCKY—SO₂

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
That portion of Boyd County south of UTM northing line 4251km.				X

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[FR Doc. 06-4820 Filed 5-23-06; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2004-0441; FRL-8174-5]

RIN 2060-AI66

National Emission Standards for the Printing and Publishing Industry

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on amendments to the national emission standards for hazardous air pollutants (NESHAP) for the printing and publishing industry which were promulgated on May 30, 1996, under the authority of section 112 of the Clean Air Act (CAA). The direct final rule amendments amend specific provisions in the Printing and Publishing Industry NESHAP to resolve issues and questions raised after promulgation of the final rule and to correct errors in the regulatory text. This action also makes direct final rule amendments to the

Paper and Other Web Coating NESHAP and the Printing, Coating, and Dyeing of Fabric and Other Textiles NESHAP to clarify the interaction between these rules and the Printing and Publishing Industry NESHAP.

DATES: The direct final rule is effective on August 22, 2006 without further notice, unless EPA receives adverse written comment by June 23, 2006 or by July 10, 2006 if a public hearing is requested by June 5, 2006. If adverse comments are received, EPA will publish a timely withdrawal in the **Federal Register** indicating which amendments, sections or paragraphs will become effective and which are being withdrawn due to adverse comment. If anyone contacts EPA requesting to speak at a public hearing, a public hearing will be held on June 8, 2006.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2004-0441. All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly

available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Air and Radiation Docket, EPA West Building, Room B-102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air and Radiation Docket is (202) 566-1742.

Public Hearing. If a public hearing is held, it will be held at 10 a.m. at the EPA’s Environmental Research Center Auditorium, Research Triangle Park, NC, or at an alternate site nearby.

FOR FURTHER INFORMATION CONTACT: For further information contact Mr. David Salman, EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Coatings and Chemicals Group (D205-01), Research Triangle Park, NC 27711; telephone number (919) 541-0859; fax number (919) 541-0246; e-mail address: salman.dave@epa.gov.

SUPPLEMENTARY INFORMATION:

Regulated Entities. Categories and entities potentially regulated by this action include:

Category	NAICS* code	Examples of potentially regulated entities
Industry	322212	Folding Paperboard Box Manufacturing.
	322221	Coated and Laminated Packaging Paper and Plastics Film Manufacturing.
	322222	Coated and Laminated Paper Manufacturing.
	322223	Plastics, Foil, and Coated Paper Bag Manufacturing.
	322224	Uncoated Paper and Multiwall Bag Manufacturing.
	322225	Laminated Aluminum Foil Manufacturing for Flexible Packaging.
	323111	Commercial Gravure Printing.
	323112	Commercial Flexographic Printing.
	323119	Other Commercial Printing.
	326192	Resilient Floor Covering Manufacturing.

*North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether your facility is regulated by this action, you should examine the applicability criteria of the rule. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Worldwide Web (WWW). In addition to being available in the docket, an electronic copy of today's direct final NESHAP will also be available on the WWW through the Technology Transfer Network (TTN). Following the Administrator's signature, a copy of the NESHAP will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules at <http://www.epa.gov/ttn/oarpg/>. The TTN at EPA's Web site provides information and technology exchange in various areas of air pollution control.

Comments. We are publishing the direct final rule amendments without prior proposal because we view the amendments as noncontroversial and do not anticipate adverse comments.

However, in the Proposed Rules section of this **Federal Register** notice, we are publishing a separate document that will serve as the proposal to amend the Printing and Publishing Industry NESHAP (40 CFR part 63, subpart KK), the Paper and Other Web Coating NESHAP (40 CFR part 63, subpart JJJJ), and the Printing, Coating, and Dyeing of Fabric and Other Textiles NESHAP (40 CFR part 63, subpart OOOO) if adverse comments are filed. Instructions for submitting comments are provided in that document. If we receive any adverse comments on one or more distinct amendments, we will publish a timely withdrawal in the **Federal Register** informing the public which provisions will become effective, and which provisions are being withdrawn due to adverse comment. We will address all public comments in a subsequent final rule, should the EPA

determine to issue one. Any of the distinct amendments in today's direct final rule for which we do not receive adverse comment will become effective on the previously mentioned date. We will not institute a second comment period on the direct final rule amendments. Any parties interested in commenting must do so at this time.

Judicial Review. Under section 307(b)(1) of the CAA, judicial review of the direct final rule amendments is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by July 24, 2006. Under section 307(d)(7)(B) of the CAA, only an objection to the direct final rule amendments that was raised with reasonable specificity during the period for public comment can be raised during judicial review. Moreover, under section 307(b)(2) of the CAA, the requirements established by the direct final rule amendments may not be challenged separately in any civil or criminal proceeding brought by EPA to enforce these requirements.

Outline. The information presented in this preamble is organized as follows:

- I. Background
- II. Amendments
 - A. Applicability
 - B. Designation of Affected Source
 - C. Definitions
 - D. Standards: Publication Rotogravure Printing
 - E. Standards: Product and Packaging Rotogravure and Wide-Web Flexographic Printing
 - F. Performance Test Methods
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 - I. Reporting Requirements
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- III. Statutory and Executive Order Reviews
 - A. Executive Order 12866, Regulatory Planning and Review
 - B. Paperwork Reduction Act
 - C. Regulatory Flexibility
 - D. Unfunded Mandates Reform Act
 - E. Executive Order 13132, Federalism
 - F. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

- G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks
- H. Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
- I. National Technology Transfer and Advancement Act
- J. Congressional Review Act.

I. Background

On May 30 1996, we issued the final NESHAP for the printing and publishing industry (61 FR 27140). The final NESHAP established standards to control organic hazardous air pollutant (HAP) emissions from new and existing publication rotogravure, product and packaging rotogravure, and wide-web flexographic printing operations.

Since promulgation of the rule, various issues and questions have been raised by stakeholders and some errors have been identified in the regulatory text. Today's action includes direct final rule amendments that resolve inconsistencies, clarify language, and add additional compliance flexibility. We are also making direct final rule amendments to the Paper and Other Web Coating NESHAP (40 CFR part 63, subpart JJJJ), and the Printing, Coating, and Dyeing of Fabric and Other Textiles NESHAP (40 CFR part 63, subpart OOOO) to clarify the interaction between these rules and the Printing and Publishing Industry NESHAP (40 CFR part 63, subpart KK). None of the amendments will have any discernable effect on the stringency of the rules.

II. Amendments

The discussion in this section of the preamble pertains to the Printing and Publishing Industry NESHAP (40 CFR part 63, subpart KK) unless otherwise noted as applying to the Paper and Other Web Coating NESHAP (40 CFR part 63, subpart JJJJ) or the Printing, Coating, and Dyeing of Fabric and Other Textiles NESHAP (40 CFR part 63, subpart OOOO).

A. Applicability

The final rule contains a provision which some sources can use to establish and maintain themselves as area sources of HAP with respect to the Printing and Publishing Industry NESHAP. EPA has received many questions about whether this provision in 40 CFR 63.820(a)(2) is an optional or mandatory provision for sources that wish to establish and maintain themselves as area sources. We have added language to 40 CFR 63.820(a)(2) to emphasize that this is an optional provision. Facilities which establish and maintain themselves as area sources through other mechanisms, as described in 40 CFR 63.820(a)(7), are not subject to this subpart.

B. Designation of Affected Source

In 40 CFR 63.821(a)(3), the final rule provides an option for including "stand-alone coating equipment" in product and packaging rotogravure or wide-web flexographic printing affected sources. We have amended 40 CFR 63.821(a)(3) to now refer to "stand-alone equipment" rather than "stand-alone coating equipment." This change provides the owner or operator with more flexibility for bringing additional equipment into the product and packaging rotogravure or wide-web flexographic printing affected source. This may simplify the compliance demonstration for some affected sources because they will not need to separately quantify the materials used on stand-alone equipment in order to exclude them from the compliance demonstration as is necessary when stand-alone equipment is not part of the product and packaging rotogravure or wide-web flexographic printing affected source. This may also simplify the compliance demonstration for affected sources which vent emissions from product and packaging rotogravure or wide-web flexographic presses and from stand-alone equipment to a common control device.

Consistent with this change, we have also amended 40 CFR 63.3300(a) of the Paper and Other Web Coating NESHAP (40 CFR part 63, subpart JJJJ) to now refer to "stand-alone equipment" rather than "stand-alone coating equipment."

In response to several requests we have added options in 40 CFR 63.821(a)(4) for including narrow-web flexographic presses and in 40 CFR 63.821(a)(5) for including proof presses in product and packaging rotogravure or wide-web flexographic printing affected sources. These options may simplify the compliance demonstration for some affected sources because they will not need to separately quantify the materials used on narrow-web flexographic

presses or proof presses in order to exclude them from the compliance demonstration as is necessary when narrow-web flexographic presses and proof presses are not part of the product and packaging rotogravure or wide-web flexographic printing affected source.

We have corrected 40 CFR 63.821(a)(2)(ii)(A) to state that the total mass of materials applied by the press using product and packaging rotogravure "print" stations be included in the numerator. The final rule incorrectly referred to product and packaging rotogravure "work" stations in the numerator.

We have added a new 40 CFR 63.821(a)(6) to clarify that certain operations affiliated with product and packaging rotogravure or wide-web flexographic printing affected sources are part of the printing and publishing industry source category, but are not part of the product and packaging rotogravure or wide-web flexographic printing affected source. These affiliated operations include mixing or dissolving of ink or coating ingredients prior to application; ink or coating mixing for viscosity adjustment, color tint or additive blending, or pH adjustment; cleaning of ink or coating lines and line parts; handling and storage of inks, coatings and solvents; and conveyance and treatment of wastewater. Including these affiliated operations in the printing and publishing source category is consistent with 40 CFR 63.7985(d)(2) of the Miscellaneous Coating Manufacturing NESHAP (40 CFR part 63, subpart HHHHH) which exempts these affiliated operations from coverage under that rule. They were excluded from the product and packaging rotogravure or wide-web flexographic printing affected source in the final rule because they were not within the scope of the data collected and used to establish the floor and the maximum achievable control technology (MACT) standard for these affected sources.

These affiliated operations continue to be part of publication rotogravure affected sources as described in 40 CFR 63.821(a)(1). The material balance records kept for the solvent recovery systems used by all publication rotogravure facilities were broader in scope and included these affiliated operations. As a result, they form part of the basis for the floor and the MACT standard for publication rotogravure affected sources.

We have added a new 40 CFR 63.821(a)(7) to clarify that certain lithographic presses, letterpress presses, or screen printing presses, referred to in this new paragraph as "other presses," are part of the printing and publishing

industry source category, but are not part of the publication rotogravure affected source or the product and packaging rotogravure or wide-web flexographic printing affected source unless the owner or operator chooses to include them in the affected source as stand-alone equipment as provided in 40 CFR 63.821(a)(3). A definition of the term "other presses" has been added to the rule.

Rotogravure, flexography, lithography, letterpress, and screen printing were all part of the printing and publishing source category in the "Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990" published on July 16, 1992 (57 FR 31576). The source category was described in detail in "Documentation for Developing the Initial Source Category List" (EPA-450/3-91-030, July 1992). The publication rotogravure affected source in the final rule addresses the publication rotogravure printing process. The product and packaging rotogravure or wide-web flexographic printing affected source in the final rule addresses the product and packaging rotogravure and wide-web flexographic printing processes. Lithography, letterpress, and screen printing are different printing processes than publication rotogravure, product and packaging rotogravure, and flexographic printing. Lithographic, letterpress, and screen printing presses that did not also meet the definition of rotogravure press or wide-web flexographic press (*i.e.*, that had no rotogravure print stations and no wide-web flexographic print stations), therefore, were not part of the publication rotogravure affected source, or the product and packaging rotogravure or wide-web flexographic printing affected source in the final rule.

We have added a new 40 CFR 63.821(a)(8) to clarify that narrow-web flexographic presses are part of the printing and publishing industry source category, but are not part of the publication rotogravure affected source or the product and packaging rotogravure or wide-web flexographic printing affected source unless the owner or operator chooses to include them in the product and packaging rotogravure or wide-web flexographic printing affected source as provided in 40 CFR 63.821(a)(3) through (5). The rule did not previously treat narrow-web flexographic presses as part of either of these affected sources. We are providing the option of including them in the product and packaging rotogravure or wide-web flexographic printing affected source because this may simplify the compliance

demonstration for some affected sources that previously had to separately quantify the materials used on these presses in order to exclude them from the compliance demonstration.

We have added the word "affected" to 40 CFR 63.821(b)(1) and (2) to clarify that these paragraphs apply to "affected sources."

C. Definitions

We have added, removed, and revised a number of definitions in the rule. These changes add clarity and consistency to the rule.

We added a definition of "coating" to clarify that in addition to solvent-borne coatings and waterborne coatings, materials with 100 percent or near 100 percent solids such as wax coatings, wax laminations, extrusion coatings, ultra-violet cured coatings, etc., are coatings. Materials used to form unsupported substrates such as calendaring of vinyl, blown film, cast film, etc., are not coatings.

We added a definition of "flexible packaging." This term is used in the revised definition of "printing operation."

We added a definition of "narrow-web flexographic press" to complement the already existing definition of "wide-web flexographic press."

We added a definition of "other press" to complement the use of that term in 40 CFR 63.821(a)(7).

We added a definition of "publication rotogravure press" to complement the definition of "rotogravure press." This definition clarifies that a publication rotogravure press may include one or more flexographic imprinters and that a publication rotogravure press with one or more flexographic imprinters is not a flexographic press.

We added a definition of "stand-alone equipment" and removed the definition of "stand-alone coating equipment." This change provides the owner or operator with additional flexibility for bringing additional equipment into the product and packaging rotogravure or wide-web flexographic printing affected source. We also removed the definitions of "coating operation" and "coating station." Since these two terms were used only in the definition of stand-alone coating equipment and they are not used in the definition of stand-alone equipment, these two definitions are no longer needed.

We revised the definition of "certified product data sheet" (CPDS) to refer to 40 CFR 63.827(b) rather than to Method 311 or 40 CFR 63.827(b) since Method 311 is discussed in 40 CFR 63.827(b). We included volatile matter weight fraction along with solids weight

fraction in the reference to 40 CFR 63.827(c) since both of these attributes are addressed in 40 CFR 63.827(c). We also explained how a material safety data sheet may serve as a CPDS.

We revised the definition of "control device efficiency" to refer to organic HAP emissions rather than to HAP emissions. The word "organic" was inadvertently omitted from the original definition.

We revised the definitions of "flexographic press" and "rotogravure press" to clarify that the unwind or feed section may contain more than one unwind or feed station. For example, a press that prints on paper and then laminates plastic film to the paper will have an unwind or feed station for the paper, and an unwind or feed station for the plastic that is being laminated to the paper. Both are included in the unwind or feed section.

We revised the definition of "flexographic print station" to clarify the meaning of the term and to distinguish it from certain operations which take place on "other presses."

We revised the definition of "printing operation" to include fabric or other textiles for use in flexible packaging, and to exclude wood furniture components and wood building products. Fabric is printed by roller (intaglio), rotary screen, ink jet, and other printing techniques. Rotogravure and flexographic printing are not traditional fabric printing techniques because the materials used are too fluid. Today, there is some rotogravure or flexographic printing of non-woven substrates, which may meet the definition of "fabric" or "textile" in the Printing, Coating, and Dyeing of Fabrics and Other Textiles NESHAP (40 CFR part 63, subpart OOOO). This includes rotogravure or flexographic printing of fabric or other textiles for use in flexible packaging which is most appropriately covered by the Printing and Publishing Industry NESHAP (40 CFR part 63, subpart KK). Therefore, we are including rotogravure or flexographic printing of fabric or other textiles for use in flexible packaging in the definition of "printing operation" in the Printing and Publishing Industry NESHAP.

Consistent with this change, we have also amended 40 CFR 63.4281 of the Printing, Coating, and Dyeing of Fabrics and Other Textiles NESHAP (40 CFR part 63, subpart OOOO) by adding a new paragraph (d)(4) which states that equipment used to coat or print on fabric or other textiles for use in flexible packaging that is included in an affected source under the Printing and Publishing Industry NESHAP (40 CFR part 63, subpart KK) is not part of an

affected source under the Printing, Coating, and Dyeing of Fabrics and Other Textiles NESHAP.

There is some rotogravure printing of wood furniture components and wood building products. These wood printing operations are covered by the Wood Furniture Manufacturing Operations NESHAP (40 CFR part 63, subpart JJ) or the Surface Coating of Wood Building Products NESHAP (40 CFR part 63, subpart QQQQ). Therefore, we are excluding them from the definition of "printing operation" in the Printing and Publishing Industry NESHAP (40 CFR part 63, subpart KK).

We revised the definition of "proof press" by broadening it to include checking the quality of substrates, inks, or other solids-containing materials. Proof presses sometimes serve these other purposes, for example, at a paper mill or ink manufacturing facility.

We corrected the definition of "rotogravure print station" to use the term "print station" rather than the term "work station" in the body of the definition and revised this definition to clarify that other types of materials that may not be referred to by the supplier or by the user as inks can be applied by rotogravure print stations. The term "ink" in the definition in the final rule was intended to include any solids containing material since materials that might be characterized by the supplier or by the user as inks, coatings, or adhesives are applied on rotogravure print stations.

We revised the definition of "work station" to clarify that work stations are present on equipment other than rotogravure or wide-web flexographic presses. For example, work stations are present on proof presses and stand-alone equipment.

The symbol H was used in two different ways in the final rule. To resolve this inconsistency, we revised the definition of the symbol H and changed the symbol used in equation 8 from H to H_{app} . The symbol H is now defined to mean the monthly organic HAP emitted in kilograms. The symbol H_{app} is defined to mean the total monthly organic HAP applied in kilograms. Since the symbol H_{app} is only used in equation 8, we have placed the definition of H_{app} immediately after that equation.

The symbols C_i and MW_i were used only in equation 20 in the final rule. The definitions of these symbols were inconsistent with the manner in which the results of Methods 25 and 25A are expressed. The definitions referred to individual organic compounds. The results of Methods 25 and 25A, however, are expressed as carbon. We

have added a new symbol C_c for use in equation 20. The definition of C_c is consistent with the manner in which the results of Methods 25 and 25A are expressed. Since C_c is used only in equation 20, we have placed the definition of C_c immediately after that equation. The symbols MW_i and C_i are not needed and have been removed. The symbols M_f and Q_{sd} are used only in equation 20. We have moved the definitions of these symbols to immediately after that equation.

D. Standards: Publication Rotogravure Printing

We revised 40 CFR 63.824(b)(1)(i)(A) and (b)(3)(i) by inserting a comma between “varnish” and “adhesive” to clarify that these are two different types of materials.

We revised 40 CFR 63.824(b)(1)(ii)(A) and (b)(2)(ii) to clarify the continuous emission monitoring requirements for solvent recovery devices and oxidizers. For solvent recovery devices, a single continuous volumetric gas flow measurement should be sufficient since the inlet and outlet volumetric gas flow rates for a solvent recovery device are essentially equal. For oxidizers, separate continuous volumetric gas flow measurements of the inlet and outlet volumetric gas flow rates are required.

E. Standards: Product and Packaging Rotogravure and Wide-Web Flexographic Printing

We corrected the first sentence of 40 CFR 63.825(b) introductory text to refer to “organic HAP emissions” rather than to “emissions.”

We revised 40 CFR 63.825(b)(6) to use the symbol H_{app} instead of H because the symbol H is used with a different meaning elsewhere in the final rule. We defined H_{app} in 40 CFR 63.825(b)(6) in the same way in which H was previously used in this paragraph of the final rule.

We revised 40 CFR 63.825(c)(2)(iii) and (d)(2) to clarify the continuous emission monitoring requirements for solvent recovery devices and oxidizers. For solvent recovery devices, a single continuous volumetric gas flow measurement should be sufficient since the inlet and outlet volumetric gas flow rates for a solvent recovery device are essentially equal. For oxidizers, separate continuous volumetric gas flow measurements of the inlet and outlet volumetric gas flow rates are required.

We revised 40 CFR 63.825(d)(1)(iv) to refer to a common oxidizer rather than a common solvent recovery system because 40 CFR 63.825(d) describes compliance demonstration requirements for oxidizers.

F. Performance Test Methods

We revised 40 CFR 63.827(a)(1)(i) and (ii) to clarify that there must be continuous emission monitors for both total organic volatile matter concentration and volumetric gas flow rate, and that the continuous emission monitoring must be done in accordance with the requirements of this subpart. Both concentration and flow data are needed to calculate the total organic volatile matter mass flow.

In 40 CFR 63.827(b) of the final rule, the provisions for using manufacturers formulation data for determining organic HAP content required the inclusion of all HAP present at a level greater than 0.1 weight percent in any raw material used. This requirement was based on indications from ink and coating manufacturers that they were already receiving this level of information from their raw material suppliers. A trade association representing certain raw material suppliers submitted information showing that ink and coating manufacturers are not receiving this level of information from their suppliers. Rather, they are receiving information consistent with the requirements of the Occupational Safety and Health Administration (OSHA) hazard communication standards which require the identification of hazardous constituents present at greater than or equal to 0.1 weight percent for OSHA-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and greater than or equal to 1.0 weight percent for other hazardous constituents. We revised 40 CFR 63.827(b) to make it consistent with the OSHA hazard communication standards, included some examples, and clarified that test data and formulation data can be provided by suppliers or independent third parties.

We revised 40 CFR 63.827(c) by including some examples, specifying how to calculate weight solids fraction from volatile matter weight fraction, and clarifying that test data and formulation data can be provided by suppliers or independent third parties.

We revised 40 CFR 63.827(d)(1)(vi) to clarify that the same method must be used to determine inlet and outlet organic volatile matter concentration, and that the 50 parts per million by volume levels for Method 25A are expressed on an as carbon basis.

We revised 40 CFR 63.827(d)(1)(viii) to clarify that the results of Methods 25 and 25A are expressed on an as carbon basis and to define the symbols used in equation 20 immediately after that equation.

In 40 CFR 63.827(e)(1) and (2) the final rule referred to the capture efficiency procedures in appendix B to 40 CFR 52.741 and 40 CFR 52.741(a)(4)(iii)(B). We revised 40 CFR 63.827(e)(1) and (2) to refer to Methods 204 and 204A through F of 40 CFR part 51, appendix M. These methods did not exist when the final rule was published on May 30, 1996. They are updated versions of the procedures specified in the final rule.

G. Monitoring Requirements

We revised 40 CFR 63.828(a)(3) to clarify that there must be continuous emission monitors for both total organic volatile matter concentration and volumetric gas flow rate. Both concentration and flow data are needed to calculate the total organic volatile matter mass flow.

H. Recordkeeping Requirements

We corrected 40 CFR 63.829(e)(1) and (2) to state that records must be kept of the total mass, as opposed to volume, of each material applied on product and packaging rotogravure or wide-web flexographic printing presses during each month. This is consistent with 40 CFR 63.821(b)(2) and 40 CFR 63.827(b)(2) which require these measurements to be done on a mass basis.

I. Reporting Requirements

We revised 40 CFR 63.830(b)(6) to clarify that summary reports are required even if the affected source does not have any control devices or does not take the performance of any control devices into account in demonstrating compliance with the emission limitations in 40 CFR 63.824 or 40 CFR 63.825. As stated in 40 CFR 63.830(b)(6)(i) through (iv), these summary reports must include information about various types of exceedances. These types of exceedances can occur at sources with or without control devices.

J. Appendix A to 40 CFR Part 63, Subpart KK

We revised appendix A to subpart KK to make several clarifications. In paragraph 3.2 of appendix A we have clarified that the confidence intervals are two-sided, changed the designation of the table to Table A–1, changed the table references to Table A–1, and corrected the table entry for 11 valid test runs. In paragraph 4.8 of appendix A we have changed the table reference to Table A–1.

III. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether this regulatory action is “significant” and, therefore, subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Executive Order defines “significant regulatory action” as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a “significant regulatory action” under the terms of Executive Order 12866 and is, therefore, not subject to OMB review.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. This action adds clarifications and corrections to the final standards. However, OMB has previously approved the information collection requirements contained in the existing regulations (69 FR 3912, January 27, 2004) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*, and has assigned OMB control number 2060–0335 (EPA ICR No. 1739.04). A copy of the Information Collection Request (ICR) may be obtained from Ms. Susan Auby by mail at the Office of Environmental Information, Collection Strategies Division (2822), EPA, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, by e-mail at auby.susan@epa.gov, or by calling (202) 566–1672. You also may download a copy from the internet at <http://www.epa.gov/icr>. Include the ICR number in any correspondence.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a

Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations are listed in 40 CFR part 9.

C. Regulatory Flexibility Analysis

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with the direct final rule amendments.

For purposes of assessing the impacts of today’s direct final rule on small entities, small entity is defined as: (1) A small business ranging from 500 to 1,000 as defined by the Small Business Administration’s regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impact of today’s direct final rule amendments on small entities, EPA has concluded that this action will not have a significant economic impact on a substantial number of small entities. We conducted an assessment of the impact of the May 30, 1996 final rule on small businesses within the industries affected by that rule. This analysis allowed us to conclude that there would not be a significant economic impact on a substantial number of small entities from the implementation of that rule. There is nothing contained in the direct final rule amendments that will impose an economic impact on small businesses in any way not considered in the analysis of the May 30, 1996 final rule; this means that the direct final rule amendments have no incremental economic impact on small businesses beyond what was already examined in the final rule.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with “Federal mandates” that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any 1 year. Before promulgating a rule for which a written statement is needed, section 205 of the UMRA generally requires us to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows us to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that the direct final rule amendments do not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. The direct final rule amendments apply to affected sources in the printing and publishing industry and clarify and correct errors in the final rule and, therefore, add no additional burden on sources. Thus, the direct final rule amendments are not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132, Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10,

1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that 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.”

The direct final rule amendments do not have federalism implications. They will 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. No printing and publishing facilities subject to the direct final rule amendments are owned by State or local governments. Therefore, State and local governments will not have any direct compliance costs resulting from the direct final rule amendments. Furthermore, the direct final rule amendments do not require these governments to take on any new responsibilities. Thus, Executive Order 13132 does not apply to the direct final rule amendments.

F. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” The direct final rule amendments do not have tribal implications as specified in Executive Order 13175. They will not have substantial direct effects on tribal governments, 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, because we are not aware of any Indian tribal governments or communities affected by the direct final rule amendments. Thus, Executive Order 13175 does not apply to the direct final rule amendments.

EPA specifically solicits additional comment on the direct final rule amendments from tribal officials.

G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be “economically significant” as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. The direct final rule amendments are not subject to Executive Order 13045 because they are based on technology performance and not on health or safety risks.

H. Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

The direct final rule amendments are not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because they are not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. VCS are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable VCS.

These amendments add references to EPA Methods 204 and 204A through F of 40 CFR part 51, appendix M for determining capture efficiency. These methods replace the capture efficiency procedures of appendix B to 40 CFR 52.741 and 40 CFR 52.741(a)(4)(iii)(B). EPA Methods 204 and 204A through F

are updated versions of the previously used procedures.

Consistent with the NTTAA, EPA conducted searches to identify VCS in addition to these EPA methods. No applicable VCS were identified for EPA Methods 204 and 204A–F. The search and review results have been documented and are placed in the docket for the amendments.

EPA test methods included in the rule are specified in 40 CFR 63.827. Under 40 CFR 63.7(f) and 40 CFR 63.8(f) of subpart A of the General Provisions, a source may apply to EPA for permission to use alternative test methods or alternative monitoring requirements in place of any of the EPA testing methods, performance specifications, or procedures.

J. Congressional Review Act

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 the direct final rule amendments and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to publication of the direct final rule amendments in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. The direct final rule amendments are not a “major rule” as defined by 5 U.S.C. 804(2). The direct final rule amendments will be effective on August 22, 2006.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, and Reporting and recordkeeping requirements.

Dated: May 18, 2006.

Stephen L. Johnson,
Administrator.

■ For the reasons set out in the preamble, Title 40, chapter I, part 63 of the Code of Federal Regulations 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 KK—[Amended]

■ 2. Section 63.820 is amended by revising paragraph (a)(2) introductory text to read as follows:

§ 63.820 Applicability.

(a) * * *

(2) Each new and existing facility at which publication rotogravure, product and packaging rotogravure, or wide-web flexographic printing presses are operated for which the owner or operator chooses to commit to and meets the criteria of paragraphs (a)(2)(i) and (ii) of this section for purposes of establishing the facility to be an area source of HAP with respect to this subpart. A facility which establishes area source status through some other mechanism, as described in paragraph (a)(7) of this section, is not subject to the provisions of this subpart.

* * * * *

■ 3. Section 63.821 is amended by:

■ a. Revising paragraphs (a)(1), (a)(2) introductory text, (a)(2)(i), (a)(2)(ii)(A), and (a)(3).

■ b. Adding paragraphs (a)(4) through (a)(8).

■ c. Revising paragraphs (b)(1) and (b)(2) to read as follows:

§ 63.821 Designation of Affected Sources.

(a) * * *

(1) All of the publication rotogravure presses and all related equipment, including proof presses, cylinder and parts cleaners, ink and solvent mixing and storage equipment, and solvent recovery equipment at a facility.

(2) All of the product and packaging rotogravure or wide-web flexographic printing presses at a facility plus any other equipment at that facility which the owner or operator chooses to include in accordance with paragraphs (a)(3) or (a)(4) of this section, except

(i) Proof presses, unless the owner or operator chooses to include proof presses in the affected source in accordance with paragraph (a)(5) of this section.

(ii) * * *

(A) the sum of the total mass of inks, coatings, varnishes, adhesives, primers, solvents, thinners, reducers, and other materials applied by the press using product and packaging rotogravure print stations and the total mass of inks, coatings, varnishes, adhesives, primers, solvents, thinners, reducers, and other materials applied by the press using wide-web flexographic print stations in each month never exceeds 5 percent of the total mass of inks, coatings, varnishes, adhesives, primers, solvents, thinners, reducers, and other materials applied by the press in that month,

including all inboard and outboard stations; and

* * * * *

(3) The owner or operator of an affected source, as defined in paragraph (a)(2) of this section, may elect to include in that affected source stand-alone equipment subject to the following provisions:

(i) Stand-alone equipment meeting any of the criteria specified in this subparagraph is eligible for inclusion:

(A) The stand-alone equipment and one or more product and packaging rotogravure or wide-web flexographic presses are used to apply solids-containing materials to the same web or substrate; or

(B) The stand-alone equipment and one or more product and packaging rotogravure or wide-web flexographic presses apply a common solids-containing material; or

(C) A common control device is used to control organic HAP emissions from the stand-alone equipment and from one or more product and packaging rotogravure or wide-web flexographic printing presses;

(ii) All eligible stand-alone equipment located at the facility is included in the affected source; and

(iii) No product and packaging rotogravure or wide-web flexographic presses are excluded from the affected source under the provisions of paragraph (a)(2)(ii) of this section.

(4) The owner or operator of an affected source, as defined in paragraph (a)(2) of this section, may elect to include in that affected source narrow-web flexographic presses subject to the following provisions:

(i) Each narrow-web flexographic press meeting any of the criteria specified in this subparagraph is eligible for inclusion:

(A) The narrow-web flexographic press and one or more product and packaging rotogravure or wide-web flexographic presses are used to apply solids containing material to the same web or substrate; or

(B) The narrow-web flexographic press and one or more product and packaging rotogravure or wide-web flexographic presses apply a common solids-containing material; or

(C) A common control device is used to control organic HAP emissions from the narrow-web flexographic press and from one or more product and packaging rotogravure or wide-web flexographic presses; and

(ii) All eligible narrow-web flexographic presses located at the facility are included in the affected source.

(5) The owner or operator of an affected source, as defined in paragraph (a)(2) of this section, may elect to include in that affected source rotogravure proof presses or flexographic proof presses subject to the following provisions:

(i) Each proof press meeting any of the criteria specified in this subparagraph is eligible for inclusion.

(A) The proof press and one or more product and packaging rotogravure or wide-web flexographic presses apply a common solids-containing material; or

(B) A common control device is used to control organic HAP emissions from the proof press and from one or more product and packaging rotogravure or wide-web flexographic presses; and

(ii) All eligible proof presses located at the facility are included in the affected source.

(6) Affiliated operations such as mixing or dissolving of ink or coating ingredients prior to application; ink or coating mixing for viscosity adjustment, color tint or additive blending, or pH adjustment; cleaning of ink or coating lines and line parts; handling and storage of inks, coatings, and solvents; and conveyance and treatment of wastewater are part of the printing and publishing industry source category, but are not part of the product and packaging rotogravure or wide-web flexographic printing affected source.

(7) Other presses are part of the printing and publishing industry source category, but are not part of the publication rotogravure affected source or the product and packaging rotogravure or wide-web flexographic printing affected source and are, therefore, exempt from the requirements of this subpart except as provided in paragraph (a)(3) of this section.

(8) Narrow web-flexographic presses are part of the printing and publishing industry source category, but are not part of the publication rotogravure affected source or the product and packaging rotogravure or wide-web flexographic printing affected source and are, therefore, exempt from the requirements of this subpart except as provided in paragraphs (a)(3) through (5) of this section.

(b) * * *

(1) The owner or operator of the affected source applies no more than 500 kilograms (kg) per month, for every month, of inks, coatings, varnishes, adhesives, primers, solvents, thinners, reducers, and other materials on product and packaging rotogravure or wide-web flexographic printing presses, or

(2) The owner or operator of the affected source applies no more than

400 kg per month, for every month, of organic HAP on product and packaging rotogravure or wide-web flexographic printing presses.

* * * * *

■ 4. Section 63.822 is amended by:

■ a. Adding in alphabetical order in paragraph (a) definitions for “coating,” “flexible packaging,” “narrow-web flexographic press,” “other press,” “publication rotogravure press,” and “stand-alone equipment.”

■ b. Removing the definitions of “coating operation,” “coating station,” and “stand-alone coating equipment” from paragraph (a).

■ c. Revising the definitions in paragraph (a) of “certified product data sheet (CPDS),” “control device efficiency,” “flexographic press,” “flexographic print station,” “printing operation,” “proof press,” “rotogravure press,” “rotogravure print station,” and “work station.”

■ d. Revising paragraph (b)(12).

■ e. Removing and reserving paragraphs (b)(6), (b)(22), (b)(32), and (b)(36) to read as follows:

§ 63.822 Definitions.

(a) * * *
* * * * *

Certified product data sheet (CPDS) means documentation furnished by suppliers of inks, coatings, varnishes, adhesives, primers, solvents, and other materials or by an independent third party that provides the organic HAP weight fraction of these materials determined in accordance with § 63.827(b), or the volatile matter weight fraction or solids weight fraction determined in accordance with § 63.827(c). A material safety data sheet (MSDS) may serve as a CPDS provided the MSDS meets the data requirements of § 63.827(b) and (c). The purpose of the CPDS is to assist the owner or operator in demonstrating compliance with the emission limitations presented in §§ 63.824–63.825.

Coating means material applied onto or impregnated into a substrate for decorative, protective, or functional purposes. Such materials include, but are not limited to, solvent-borne coatings, waterborne coatings, wax coatings, wax laminations, extrusion coatings, extrusion laminations, 100 percent solid adhesives, ultra-violet cured coatings, electron beam cured coatings, hot melt coatings, and cold seal coatings. Materials used to form unsupported substrates such as calendaring of vinyl, blown film, cast film, extruded film, and coextruded film are not considered coatings.

* * * * *

Control device efficiency means the ratio of organic HAP emissions recovered or destroyed by a control device to the total organic HAP emissions that are introduced into the control device, expressed as a percentage.

* * * * *

Flexible packaging means any package or part of a package the shape of which can be readily changed. Flexible packaging includes, but is not limited to, bags, pouches, labels, liners and wraps utilizing paper, plastic, film, aluminum foil, metalized or coated paper or film, or any combination of these materials.

Flexographic press means an unwind or feed section, which may include more than one unwind or feed station (such as on a laminator), a series of individual work stations, one or more of which is a flexographic print station, any dryers (including interstage dryers and overhead tunnel dryers) associated with the work stations, and a rewind, stack, or collection section. The work stations may be oriented vertically, horizontally, or around the circumference of a single large impression cylinder. Inboard and outboard work stations, including those employing any other technology, such as rotogravure, are included if they are capable of printing or coating on the same substrate. A publication rotogravure press with one or more flexographic imprinters is not a flexographic press.

Flexographic print station means a print station on which a flexographic printing operation is conducted. A flexographic print station includes an anilox roller that transfers material to a raised image (type or art) on a plate cylinder. The material is then transferred from the image on the plate cylinder to the web or sheet to be printed. A flexographic print station may include a fountain roller to transfer material from the reservoir to the anilox roller, or material may be transferred directly from the reservoir to the anilox roller. The materials applied are of a fluid, rather than paste, consistency.

* * * * *

Narrow-web flexographic press means a flexographic press that is not capable of printing substrates greater than 18 inches in width and that does not also meet the definition of rotogravure press (i.e., it has no rotogravure print stations).

* * * * *

Other press means a lithographic press, letterpress press, or screen printing press that does not meet the definition of rotogravure press or

flexographic press (i.e., it has no rotogravure print stations and no flexographic print stations), and that does not print on fabric or other textiles as defined in the Printing, Coating, and Dyeing of Fabrics and Other Textiles NESHAP (40 CFR part 63, subpart OOOO), wood furniture components as defined in the Wood Furniture Manufacturing Operations NESHAP (40 CFR part 63, subpart JJ) or wood building products as defined in the Surface Coating of Wood Building Products NESHAP (40 CFR part 63, subpart QQQQ).

* * * * *

Printing operation means the formation of words, designs, or pictures on a substrate other than wood furniture components as defined in the Wood Furniture Manufacturing Operations NESHAP (40 CFR part 63, subpart JJ), wood building products as defined in the Surface Coating of Wood Building Products NESHAP (40 CFR part 63, subpart QQQQ), and fabric or other textiles as defined in the Printing, Coating, and Dyeing of Fabric and Other Textiles NESHAP (40 CFR part 63, subpart OOOO), except for fabric or other textiles for use in flexible packaging.

* * * * *

Proof press means any press which prints only non-saleable items used to check the quality of image formation of rotogravure cylinders or flexographic plates; substrates such as paper, plastic film, metal foil, or vinyl; or ink, coating varnish, adhesive, primer, or other solids-containing material.

* * * * *

Publication rotogravure press means a rotogravure press used for publication rotogravure printing. A publication rotogravure press may include one or more flexographic imprinters. A publication rotogravure press with one or more flexographic imprinters is not a flexographic press.

* * * * *

Rotogravure press means an unwind or feed section, which may include more than one unwind or feed station (such as on a laminator), a series of individual work stations, one or more of which is a rotogravure print station, any dryers associated with the work stations, and a rewind, stack, or collection section. Inboard and outboard work stations, including those employing any other technology, such as flexography, are included if they are capable of printing or coating on the same substrate.

Rotogravure print station means a print station on which a rotogravure printing operation is conducted. A

rotogravure print station includes a rotogravure cylinder and supply for ink or other solids containing material. The image (type and art) to be printed is etched or engraved below the surface of the rotogravure cylinder. On a rotogravure cylinder the printing image consists of millions of minute cells.

Stand-alone equipment means an unwind or feed section, which may include more than one unwind or feed station (such as on a laminator); a series of one or more work stations and any associated dryers; and a rewind, stack, or collection section that is not part of a product and packaging rotogravure or wide-web flexographic press. Stand-alone equipment is sometimes referred to as "off-line" equipment.

Work station means a unit on which material is deposited onto a substrate.

- (b) [Reserved]
- (6) [Reserved]
- (12) H = the monthly organic HAP emitted, kg.
- (22) [Reserved]
- (32) [Reserved]
- (36) [Reserved]

■ 5. Section 63.824 is amended by revising paragraphs (b)(1)(i)(A), (b)(1)(ii)(A), (b)(2)(ii), and (b)(3)(i) to read as follows:

§ 63.824 Standards: Publication rotogravure printing.

- (b) [Reserved]
- (1) [Reserved]
- (i) [Reserved]
- (A) Measure the mass of each ink, coating, varnish, adhesive, primer, solvent, and other material used by the affected source during the month.

(ii) [Reserved]

(A) Install continuous emission monitors to collect the data necessary to calculate the total organic volatile matter mass flow in the gas stream entering and the total organic volatile matter mass flow in the gas stream exiting the solvent recovery device for each month such that the percent control efficiency (E) of the solvent recovery device can be calculated for the month. This requires continuous emission monitoring of the total organic volatile matter concentration in the gas stream entering the solvent recovery device, the total organic volatile matter

concentration in the gas stream exiting the solvent recovery device, and the volumetric gas flow rate through the solvent recovery device. A single continuous volumetric gas flow measurement should be sufficient for a solvent recovery device since the inlet and outlet volumetric gas flow rates for a solvent recovery device are essentially equal. Each month's individual inlet concentration values and corresponding individual gas flow rate values are multiplied and then summed to get the total organic volatile matter mass flow in the gas stream entering the solvent recovery device for the month. Each month's individual outlet concentration values and corresponding individual gas flow rate values are multiplied and then summed to get the total organic volatile matter mass flow in the gas stream exiting the solvent recovery device for the month.

- (2) [Reserved]
- (ii) Use continuous emission monitors, conduct an initial performance test of capture efficiency, and continuously monitor a site specific operating parameter to assure capture efficiency. The percent control efficiency of the oxidizer shall be demonstrated in accordance with the requirements of paragraph (b)(1)(ii) of this section except that separate continuous measurements of the inlet volumetric gas flow rate and the outlet volumetric gas flow rate are required for an oxidizer.

(3) [Reserved]

(i) Measure the mass of each ink, coating, varnish, adhesive, primer, solvent, and other material used in the affected source during the month.

- 6. Section 63.825 is amended by:
 - a. Revising the first sentence of paragraph (b) introductory text.
 - b. Revising paragraph (b)(6).
 - c. Revising paragraph (c)(2)(iii).
 - d. Revising paragraph (d)(1)(iv).
 - e. Revising paragraph (d)(2) to read as follows:

§ 63.825 Standards: Product and packaging rotogravure and wide-web flexographic printing.

(b) Each product and packaging rotogravure or wide-web flexographic printing affected source shall limit organic HAP emissions to no more than 5 percent of the organic HAP applied for the month; or to no more than 4 percent of the mass of inks, coatings, varnishes, adhesives, primers, solvents, reducers, thinners, and other materials applied for the month; or to no more than 20

percent of the mass of solids applied for the month; or to a calculated equivalent allowable mass based on the organic HAP and solids contents of the inks, coatings, varnishes, adhesives, primers, solvents, reducers, thinners, and other materials applied for the month.

(6) Demonstrate that the total monthly organic HAP applied, H_{app}, as determined by Equation 8, is less than the calculated equivalent allowable organic HAP, H_a, as determined by paragraph (e) of this section.

$$H_{app} = \sum_{i=1}^p M_i C_{hi} + \sum_{j=1}^q M_j C_{hj} \quad \text{Eq. 8}$$

Where:
H_{app} = Total monthly organic HAP applied, kg.

- (c) [Reserved]
- (2) [Reserved]
- (iii) Install continuous emission monitors to collect the data necessary to calculate the total organic volatile matter mass flow in the gas stream entering and the total organic volatile mass flow in the gas stream exiting the solvent recovery device for each month such that the percent control efficiency (E) of the solvent recovery device can be calculated for the month. This requires continuous emission monitoring of the total organic volatile matter concentration in the gas stream entering the solvent recovery device, the total organic volatile matter concentration in the gas stream exiting the solvent recovery device, and the volumetric gas flow rate through the solvent recovery device. A single continuous volumetric gas flow measurement should be sufficient for a solvent recovery device since the inlet and outlet volumetric gas flow rates for a solvent recovery device are essentially equal. Each month's individual inlet concentration values and corresponding individual gas flow rate values are multiplied and then summed to get the total organic volatile matter mass flow in the gas stream entering the solvent recovery device for the month. Each month's individual outlet concentration values and corresponding individual gas flow rate values are multiplied and then summed to get the total organic volatile matter mass flow in the gas stream exiting the solvent recovery device for the month.
- (d) [Reserved]
- (1) [Reserved]
- (iv) If demonstrating compliance on the basis of organic HAP emission rate based on solids applied, organic HAP emission rate based on materials

applied, or emission of less than the calculated allowable organic HAP, measure the mass of each ink, coating, varnish, adhesive, primer, solvent, and other material applied on the press or group of presses controlled by a common control device during the month.

* * * * *

(2) Use continuous emission monitors, conduct an initial performance test of capture efficiency, and continuously monitor a site specific operating parameter to assure capture efficiency. The percent control efficiency of the oxidizer shall be demonstrated in accordance with the requirements of paragraph (c)(2) of this section except that separate continuous volumetric gas flow measurements of the inlet and outlet volumetric gas flow rates are required for an oxidizer.

* * * * *

■ 7. Section 63.827 is amended by:

- a. Revising paragraphs (a)(1)(i) and (a)(1)(ii).
- b. Revising paragraph (b).
- c. Revising paragraph (c).
- d. Revising paragraphs (d)(1)(vi) and (d)(1)(viii).
- e. Revising paragraphs (e)(1) and (e)(2) to read as follows:

§ 63.827 Performance Test Methods.

(a) * * *

(1) * * *

(i) It is equipped with continuous emission monitors for determining total organic volatile matter concentration and the volumetric gas flow rate, and capture efficiency has been determined in accordance with the requirements of this subpart, such that an overall organic HAP control efficiency can be calculated, and

(ii) The continuous emission monitors are used to demonstrate continuous compliance in accordance with § 63.824(b)(1)(ii), § 63.825(b)(2)(ii), § 63.825(c)(2), or § 63.825(d)(2), as applicable, and § 63.828, or

* * * * *

(b) Determination of the weight fraction organic HAP of inks, coatings, varnishes, adhesives, primers, solvents, thinners, reducers, diluents, and other materials used by a publication rotogravure affected source shall be conducted according to paragraph (b)(1) of this section. Determination of the weight fraction organic HAP of inks, coatings, varnishes, adhesives, primers, solvents, thinners, reducers, diluents, and other materials applied by a product and packaging rotogravure or wide-web flexographic printing affected source shall be conducted according to paragraph (b)(2) of this section. If the

weight fraction organic HAP values are not determined using the procedures in paragraphs (b)(1) or (b)(2) of this section, the owner or operator must submit an alternative test method for determining their values for approval by the Administrator in accordance with § 63.7(f). The recovery efficiency of the test method must be determined for all of the target organic HAP and a correction factor, if necessary, must be determined and applied.

(1) Each owner or operator of a publication rotogravure affected source shall determine the weight fraction organic HAP of each ink, coating, varnish, adhesive, primer, solvent, and other material used by following one of the procedures in paragraphs (b)(1)(i) through (iii) of this section:

(i) The owner or operator may test the material in accordance with Method 311 of appendix A of this part. The Method 311 determination may be performed by the owner or operator of the affected source, the supplier of the material, or an independent third party. The organic HAP content determined by Method 311 must be calculated according to the criteria and procedures in paragraphs (b)(1)(i)(A) through (C) of this section.

(A) Include each organic HAP determined to be present at greater than or equal to 0.1 weight percent for Occupational Safety and Health Administration (OSHA)-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and greater than or equal to 1.0 weight percent for other organic HAP compounds.

(B) Express the weight fraction of each organic HAP included according to paragraph (b)(1)(i)(A) of this section as a value truncated to four places after the decimal point (for example, 0.3791).

(C) Calculate the total weight fraction of organic HAP in the tested material by summing the weight fraction of each organic HAP included according to paragraph (b)(1)(i)(A) of this section and truncating the result to three places after the decimal point (for example, 0.763).

(ii) The owner or operator may determine the weight fraction volatile matter of the material in accordance with § 63.827(c)(1) and use this value for the weight fraction organic HAP for all compliance purposes.

(iii) The owner or operator may use formulation data to determine the weight fraction organic HAP of a material. Formulation data may be provided to the owner or operator on a CPDS by the supplier of the material or an independent third party.

Formulation data may be used provided that the weight fraction organic HAP is calculated according to the criteria and procedures in paragraphs (b)(1)(iii)(A)

through (D) of this section. In the event of an inconsistency between the formulation data and the result of Method 311 of appendix A of this part, where the test result is higher, the Method 311 data will take precedence unless, after consultation, the owner or operator can demonstrate to the satisfaction of the enforcement agency that the formulation data are correct.

(A) For each raw material used in making the material, include each organic HAP present in that raw material at greater than or equal to 0.1 weight percent for OSHA-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and greater than or equal to 1.0 weight percent for other organic HAP compounds. The weight fraction of each such organic HAP in each raw material must be determined by Method 311 of appendix A of this part, by an alternate method approved by the Administrator, or from a CPDS provided by the raw material supplier or an independent third party. The weight fraction of each such organic HAP in each raw material must be expressed as a value truncated to four places after the decimal point (for example, 0.1291).

(B) For each raw material used in making the material, the weight fraction contribution of each organic HAP, which is included according to paragraph (b)(1)(iii)(A) of this section, in that raw material to the weight fraction organic HAP of the material is calculated by multiplying the weight fraction, truncated to four places after the decimal point (for example, 0.1291), of that organic HAP in that raw material times the weight fraction of that raw material, truncated to four places after the decimal point (for example, 0.2246), in the material. The product of each such multiplication is to be truncated to four places after the decimal point (for example, 0.1291 times 0.2246 yields 0.02899586 which truncates to 0.0289).

(C) For each organic HAP which is included according to paragraph (b)(1)(iii)(A) of this section, the total weight fraction of that organic HAP in the material is calculated by adding the weight fraction contribution of that organic HAP from each raw material in which that organic HAP is included according to paragraph (b)(1)(iii)(A) of this section. The sum of each such addition must be expressed to four places after the decimal point.

(D) The total weight fraction of organic HAP in the material is the sum of the counted individual organic HAP weight fractions. This sum must be truncated to three places after the decimal point (for example, 0.763).

(2) Each owner or operator of a product and packaging rotogravure or

wide-web flexographic printing affected source shall determine the organic HAP weight fraction of each ink, coating, varnish, adhesive, primer, solvent, and other material applied by following one of the procedures in paragraphs (b)(2)(i) through (iii) of this section:

(i) The owner or operator may test the material in accordance with Method 311 of appendix A of this part. The Method 311 determination may be performed by the owner or operator of the affected source, the supplier of the material, or an independent third party. The organic HAP content determined by Method 311 must be calculated according to the criteria and procedures in paragraphs (b)(2)(i)(A) through (C) of this section.

(A) Include each organic HAP determined to be present at greater than or equal to 0.1 weight percent for OSHA-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and greater than or equal to 1.0 weight percent for other organic HAP compounds.

(B) Express the weight fraction of each organic HAP included according to paragraph (b)(2)(i)(A) of this section as a value truncated to four places after the decimal point (for example, 0.3791).

(C) Calculate the total weight fraction of organic HAP in the tested material by summing the weight fraction of each organic HAP included according to paragraph (b)(2)(i)(A) of this section and truncating the result to three places after the decimal point (for example, 0.763).

(ii) The owner or operator may determine the weight fraction volatile matter of the material in accordance with § 63.827(c)(2) and use this value for the weight fraction organic HAP for all compliance purposes.

(iii) The owner or operator may use formulation data to determine the weight fraction organic HAP of a material. Formulation data may be provided to the owner or operator on a CPDS by the supplier of the material or an independent third party. Formulation data may be used provided that the weight fraction organic HAP is calculated according to the criteria and procedures in paragraphs (b)(2)(iii)(A) through (D) of this section. In the event of an inconsistency between the formulation data and the result of Method 311 of appendix A of this part, where the test result is higher, the Method 311 data will take precedence unless, after consultation, the owner or operator can demonstrate to the satisfaction of the enforcement agency that the formulation data are correct.

(A) For each raw material used in making the material, include each organic HAP present in that raw material at greater than or equal to 0.1 weight percent for OSHA-defined

carcinogens as specified in 29 CFR 1910.1200(d)(4) and greater than or equal to 1.0 weight percent for other organic HAP compounds. The weight fraction of each such organic HAP in each raw material must be determined by Method 311 of appendix A of this part, by an alternate method approved by the Administrator, or from a CPDS provided by the raw material supplier or an independent third party. The weight fraction of each such organic HAP in each raw material must be expressed as a value truncated to four places after the decimal point (for example, 0.1291).

(B) For each raw material used in making the material, the weight fraction contribution of each organic HAP, which is included according to paragraph (b)(2)(iii)(A) of this section, in that raw material to the weight fraction organic HAP of the material is calculated by multiplying the weight fraction, truncated to four places after the decimal point (for example, 0.1291), of that organic HAP in that raw material times the weight fraction of that raw material, truncated to four places after the decimal point (for example, 0.2246), in the material. The product of each such multiplication is truncated to four places after the decimal point (for example, 0.1291 times 0.2246 yields 0.02899586 which truncates to 0.0289).

(C) For each organic HAP which is included according to paragraph (b)(2)(iii)(A) of this section, the total weight fraction of that organic HAP in the material is calculated by adding the weight fraction contribution of that organic HAP from each raw material in which that organic HAP is included according to paragraph (b)(2)(iii)(A) of this section. The sum of each such addition must be expressed to four places after the decimal point.

(D) The total weight fraction of organic HAP in the material is the sum of the counted individual organic HAP weight fractions. This sum is to be truncated to three places after the decimal point (for example, 0.763).

(c) Determination of the weight fraction volatile matter content of inks, coatings, varnishes, adhesives, primers, solvents, reducers, thinners, diluents, and other materials used by a publication rotogravure affected source shall be conducted according to paragraph (c)(1) of this section. Determination of the weight fraction volatile matter content and weight fraction solids content of inks, coatings, varnishes, adhesives, primers, solvents, reducers, thinners, diluents, and other materials applied by a product and packaging rotogravure or wide-web flexographic printing affected source

shall be conducted according to paragraph (c)(2) of this section.

(1) Each owner or operator of a publication rotogravure affected source shall determine the volatile matter weight fraction of each ink, coating, varnish, adhesive, primer, solvent, reducer, thinner, diluent, and other material used by following the procedures in paragraph (b)(1)(i) of this section, or by using formulation data as described in paragraph (c)(3) of this section.

(i) Determine the volatile matter weight fraction of the material using Method 24A of 40 CFR part 60, appendix A. The Method 24A determination may be performed by the owner or operator of the affected source, the supplier of the material, or an independent third party. The Method 24A result shall be truncated to three places after the decimal point (for example, 0.763). If these values cannot be determined using Method 24A, the owner or operator shall submit an alternative technique for determining their values for approval by the Administrator.

(2) Each owner or operator of a product and packaging rotogravure or wide-web flexographic printing affected source shall determine the volatile matter weight fraction and solids weight fraction of each ink, coating, varnish, adhesive, primer, solvent, reducer, thinner, diluent, and other material applied by following the procedures in paragraphs (b)(2)(i) and (ii) of this section, or by using formulation data as described in paragraph (c)(3) of this section.

(i) Determine the volatile matter weight fraction of the material using Method 24 of 40 CFR part 60, appendix A. The Method 24 determination may be performed by the owner or operator of the affected source, the supplier of the material, or an independent third party. The Method 24 result shall be truncated to three places after the decimal point (for example, 0.763). If these values cannot be determined using Method 24, the owner or operator shall submit an alternative technique for determining their values for approval by the Administrator.

(ii) Calculate the solids weight fraction Method 24 result by subtracting the volatile matter weight fraction Method 24 result from 1.000. This calculation may be performed by the owner or operator, the supplier of the material, or an independent third party.

(3) The owner or operator may use formulation data to determine the volatile matter weight fraction or solids weight fraction of a material. Formulation data may be provided to

the owner or operator on a CPDS by the supplier of the material or an independent third party. The volatile matter weight fraction and solids weight fraction shall be truncated to three places after the decimal point (for example, 0.763). In the event of any inconsistency between the formulation data and the result of Method 24 or Method 24A of 40 CFR part 60, appendix A, where the test result for volatile matter weight fraction is higher or the test result for solids weight fraction is lower, the applicable test method data will take precedence unless, after consultation, the owner or operator can demonstrate to the satisfaction of the enforcement agency that the formulation data are correct.

(d) * * *

(1) * * *

(vi) Method 25 of 40 CFR part 60, appendix A, shall be used to determine organic volatile matter concentration, except as provided in paragraphs (d)(1)(vi)(A) through (D) of this section. The owner or operator shall submit notice of the intended test method to the Administrator for approval along with notice of the performance test required under § 63.7(c). The same method must be used for both the inlet and outlet measurements. The owner or operator may use Method 25A of 40 CFR part 60, appendix A, if (A) An exhaust gas organic volatile matter concentration of 50 parts per million by volume (ppmv) or less as carbon is required to comply with the standards of §§ 63.824–63.825, or

(B) The organic volatile matter concentration at the inlet to the control system and the required level of control are such to result in exhaust gas organic volatile matter concentrations of 50 ppmv or less as carbon, or

(C) Because of the high efficiency of the control device, the anticipated organic volatile matter concentration at the control device exhaust is 50 ppmv or less as carbon, regardless of inlet concentration, or

(D) The control device is not an oxidizer.

* * * * *

(viii) Organic volatile matter mass flow rates shall be determined using Equation 20:

$$M_f = Q_{sd} C_c [12.0] [0.0416] [10^{-6}] \quad \text{Eq. 20}$$

Where:

M_f = Total organic volatile matter mass flow rate, kg/hour (h).

Q_{sd} = Volumetric flow rate of gases entering or exiting the control device, as determined according to § 63.827(d)(1)(ii), dry standard cubic meters (dscm)/h.

C_c = Concentration of organic compounds as carbon, ppmv.

12.0 = Molecular weight of carbon.

0.0416 = Conversion factor for molar volume, kg-moles per cubic meter (mol/m³) (@ 293 Kelvin (K) and 760 millimeters of mercury (mmHg)).

* * * * *

(e) * * *

(1) You may assume your capture efficiency equals 100 percent if your capture system is a permanent total enclosure (PTE). You must confirm that your capture system is a PTE by demonstrating that it meets the requirements of section 6 of Method 204 of 40 CFR part 51, appendix M, and that all exhaust gases from the enclosure are delivered to a control device.

(2) You may determine capture efficiency according to the protocols for testing with temporary total enclosures that are specified in Methods 204 and 204A through F of 40 CFR part 51, appendix M. You may exclude never controlled work stations from such capture efficiency determinations.

* * * * *

■ 8. Section 63.828 is amended by revising paragraph (a)(3) to read as follows:

§ 63.828 Monitoring Requirements.

(a) * * *

(3) An owner or operator complying with §§ 63.824–63.825 through continuous emission monitoring of a control device shall install, calibrate, operate, and maintain continuous emission monitors to measure total organic volatile matter concentration and volumetric gas flow rate in accordance with § 63.824(b)(1)(ii), § 63.825(b)(2)(ii), § 63.825(c)(2), or § 63.825(d)(2), as applicable.

* * * * *

■ 9. Section 63.829 is amended by revising paragraphs (e)(1) and (e)(2) to read as follows:

§ 63.829 Recordkeeping Requirements.

* * * * *

(e) * * *

(1) For each facility which meets the criteria of § 63.821(b)(1), the owner or operator shall maintain records of the total mass of each material applied on product and packaging rotogravure or wide-web flexographic printing presses during each month.

(2) For each facility which meets the criteria of § 63.821(b)(2), the owner or operator shall maintain records of the total mass and organic HAP content of each material applied on product and packaging rotogravure or wide-web flexographic printing presses during each month.

* * * * *

■ 10. Section 63.830 is amended by revising paragraph (b)(6) introductory text to read as follows:

§ 63.830 Reporting Requirements.

* * * * *

(b) * * *

(6) A summary report specified in § 63.10(e)(3) of this part shall be submitted on a semi-annual basis (i.e., once every 6-month period). These summary reports are required even if the affected source does not have any control devices or does not take the performance of any control devices into account in demonstrating compliance with the emission limitations in § 63.824 or § 63.825. In addition to a report of operating parameter exceedances as required by § 63.10(e)(3)(i), the summary report shall include, as applicable:

* * * * *

■ 11. Appendix A is amended by revising paragraphs 3.2 and 4.8 to read as follows:

Appendix A to Subpart KK of Part 63—Data Quality Objective and Lower Confidence Limit Approaches for Alternative Capture Efficiency Protocols and Test Methods

* * * * *

3.2 The DQO calculation is made as follows using Equations 1 and 2:

$$P = \left[\frac{a}{x_{avg}} \right] 100 \quad \text{Eq. 1}$$

$$a = \frac{t_{0.975} S}{\sqrt{n}} \quad \text{Eq. 2}$$

Where:

a = Distance from the average measured CE value to the endpoints of the 95-percent (two-sided) confidence interval for the measured value.

n = Number of valid test runs.
 P = DQO indicator statistic, distance from the average measured CE value to the endpoints of the 95-percent (two-sided) confidence interval, expressed as a percent of the average measured CE value.
 s = Sample standard deviation.
 $t_{0.975}$ = t-value at the 95-percent (two-sided) confidence level (see Table A-1).
 x_{avg} = Average measured CE value (calculated from all valid test runs).
 x_i = The CE value calculated from the *i*th test run.

TABLE A-1.—t-VALUES

Number of valid test runs, n	$t_{0.975}$	$t_{0.90}$
1 or 2	N/A	N/A
3	4.303	1.886
4	3.182	1.638
5	2.776	1.533
6	2.571	1.476
7	2.447	1.440
8	2.365	1.415
9	2.306	1.397
10	2.262	1.383
11	2.228	1.372
12	2.201	1.363
13	2.179	1.356
14	2.160	1.350
15	2.145	1.345
16	2.131	1.341
17	2.120	1.337
18	2.110	1.333
19	2.101	1.330
20	2.093	1.328
21	2.086	1.325

* * * * *

4.8 The LCL is calculated at an 80 percent (two-sided) confidence level as follows using Equation 11:

$$LC_1 = x_{avg} - \frac{t_{0.90}S}{\sqrt{n}} \quad \text{Eq. 11}$$

Where:

LC_1 = LCL at an 80-percent (two-sided) confidence level.

n = Number of valid test runs.

s = Sample standard deviation.

$t_{0.90}$ = t-value at the 80-percent (two-sided) confidence level (see Table A-1).

x_{avg} = Average measured CE value (calculated from all valid test runs).

* * * * *

Subpart JJJJ—[Amended]

■ 12. Section 63.3300 is amended by revising paragraph (a) to read as follows:

§ 63.3300 Which of my emission sources are affected by this subpart?

* * * * *

(a) Any web coating line that is stand-alone equipment under subpart KK of

this part (National Emission Standards for the Printing and Publishing Industry) which the owner or operator includes in the affected source under subpart KK.

* * * * *

Subpart OOOO—[Amended]

■ 13. Section 63.4281 is amended by:
 ■ a. Revising paragraph (d) introductory text.

■ b. Adding paragraphs (d)(4) to read as follows:

§ 63.4281 Am I subject to this subpart?

* * * * *

(d) Web coating lines specified in paragraphs (d)(1) through (4) of this section are not part of the affected source of this subpart.

* * * * *

(4) Any web coating line that coats or prints fabric or other textiles for use in flexible packaging and that is included in an affected source under subpart KK of this part (National Emission Standards for the Printing and Publishing Industry).

* * * * *

[FR Doc. 06-4821 Filed 5-23-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 102

RIN 0906—AA60

Smallpox Vaccine Injury Compensation Program: Smallpox (Vaccinia) Vaccine Injury Table

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Adoption of interim final rule as final rule with an amendment.

SUMMARY: This document adopts the Smallpox (Vaccinia) Vaccine Injury Table (the Table) Interim Final Rule as the Final Rule with an amendment, as follows: the Final Rule clarifies that, in order for the presumption of causation to apply, the time intervals listed on the Table refer specifically to the period in which the first symptom or manifestation of onset of injury must appear following administration of the smallpox vaccine or exposure to vaccinia, and that the time intervals listed have no relevance to time of diagnosis of the injury.

DATES: The Interim Final Rule, published on August 27, 2003, was

effective on that date, and is adopted as the Final Rule with an amendment effective May 24, 2006.

FOR FURTHER INFORMATION CONTACT: Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, (301) 443-2330.

SUPPLEMENTARY INFORMATION:

Background

The Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), Pub. L. 108-20, 117 Stat. 638, directed the Secretary of Health and Human Services (the Secretary) to establish the Smallpox Vaccine Injury Compensation Program (the Program). Secondary to other payers, the Program provides medical, lost employment income, and death benefits for eligible individuals who sustained covered injuries as a result of receiving smallpox vaccine or other covered countermeasures, or as a result of accidental exposure to vaccinia. Congress appropriated \$42 million in fiscal year (FY) 2003 for the administration of, and payment of benefits under, the Program. The Consolidated Appropriations Act of 2005 reduced this appropriation to \$22 million. The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2006 (Pub. L. 109-149) further reduced the Program's appropriation by \$10 million to a total of \$12 million.

Individuals who receive a smallpox vaccination under a Department of Health and Human Services (HHS), State, or local emergency response plan approved by HHS within the period described in the Secretary's Declaration, and who sustain a covered injury may be eligible for benefits under SEPPA. Individuals who contracted vaccinia through contact with such individuals or other eligible vaccinia contacts and who sustain a covered injury may also be eligible for benefits. In the case of death resulting directly from receipt of the smallpox vaccine or exposure to vaccinia by eligible individuals, certain of their survivors may be considered for death benefits. If an eligible individual who sustained a covered injury dies from another cause before payment of benefits has been made under the Program, the estate may qualify for payment of unreimbursed medical expenses incurred and employment income lost as a result of the covered injury, secondary to other payers. SEPPA directed the Secretary to establish a table identifying adverse effects (including injuries, disabilities,